

ORIGINAL

-Application

Scott Hamilton

Proton Ctr.

CN1502-004

FEB 10 '15 PM 2:09

February 10, 2015

Melanie Hill, Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: Scott Hamilton Proton Center
Franklin, Williamson County

Dear Mrs. Hill:

This letter transmits an original and two copies of the subject application for the project which we discussed with your staff in January of this year. The affidavit and filing fee are enclosed.

I am the contact person for this project. Brant Phillips of Bass Berry | Sims is legal counsel. Please advise me of any additional information you may need. We look forward to working with the Agency on this project.

Respectfully,



R. Scott Warwick
Vice President
MTPC, LLC
6450 Provision Cares Way
Knoxville, TN 37909
Office 865.684.2613
Mobile 865.384.7636
swarwick@pvhealthcare.com

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COUNTY OF Knox


Signature/Title

Boris Gyll

My Commission expires 09/11/2024



THE TENNESSEAN

General Merchandise

CONTRACT NO.: CNM329

COUNTY: Davidson

The Tennessee Department of Transportation is about to make final settlement with the contractor for construction of the above numbered project. All persons wishing to file claims pursuant to Section 54-5-122, T.C.A. must file same with the Director of Construction, Tennessee Department of Transportation, Suite 700 James K. Polk Bldg., Nashville, Tennessee 37243-0328, on or before 03/13/15.

Public Notices

Continued from last column

CONTRACT NO.: CNM909

COUNTY: Davidson

The Tennessee Department of Transportation is about to make final settlement with the contractor for construction of the above numbered project. All persons wishing to file claims pursuant to Section 54-5-122, T.C.A. must file same with the Director of Construction, Tennessee Department of Transportation, Suite 700 James K. Polk Bldg., Nashville, Tennessee 37243-0328, on or before 03/13/15.

Public Notices

Continued from last column

Department of Transportation, Suite 700

James K. Polk Bldg., Nashville, Tennessee 37243-0328, on or before 03/20/15.

TN-400113264

Public Notices

TO DELINQUENT TAXPAYERS METROPOLITAN GOVERNMENT

FINAL NOTICE 2013

REAL PROPERTY TAX

You are advised that after March 2, 2015, additional penalties and costs will be imposed in consequence of suits to be filed for enforcement of the lien for taxes against land. Until the filing of such suits, taxes may be paid at 700 2nd Ave. South, Suite 220, Howard Office Building.

The office at 700 2nd Ave. South, Suite 220, Howard Office Building, will be open Monday - Friday from 8:00 a.m. to 4:30 p.m. to receive payment of taxes. The office will not be open on Saturday, February 28, 2015; therefore, the deadline to pay taxes has been extended to Monday, March 2, 2015.

AVOID COURT COSTS - PAY NOW

700 2nd Ave. South Suite 220
Howard Office Building
862-6330

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SAL E

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Public Notices

0000297591

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties. In accordance with T.C.A. Sections 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that The Scott Hamilton Proton Center (a facility for outpatient proton cancer therapy), to be owned by MTPC, LLC (a limited liability company) and to be managed by Provision Proton Centers, LLC (a limited liability company), intends to file an application for a Certificate of Need to establish a proton therapy center for cancer patients, to acquire major medical equipment (proton therapy equipment and related components), and to initiate outpatient proton therapy services, at an unaddressed site in Franklin (Williamson County). The site is on the east side of Carothers Parkway, between the Parkway's intersection with Physicians Way and Williamson Medical Center. The project cost is estimated at \$106,000,000. The project does not contain any other type of major medical equipment or initiate or discontinue any other health service; and it will not affect any facility's licensed bed complements.

The anticipated date of filing the application is on or before February 11, 2015. The contact person for the project is Scott Warwick, Vice President, MTPC, 6450 Provision Cares Way, Knoxville, TN 37909, 865-684-2613.

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Health Services and Development Agency
Andrew Jackson Building
500 Deaderick Street, Suite 850
Nashville, Tennessee 37243

Pursuant to TCA Sec. 68-11-1607(c)(1), (A) any health care institution wishing to oppose a Certificate of Need application must file a written objection with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled, and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

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THE SCOTT HAMILTON PROTON CENTER

**A REGIONAL FACILITY IN
MIDDLE TENNESSEE FOR
OUTPATIENT PROTON THERAPY
FOR CANCER PATIENTS**

**Certificate of Need Application
Filed February 2015**

1. **Name of Facility, Agency, or Institution**

Scott Hamilton Proton Center
Name
Unaddressed site on side of Carothers Parkway between its intersection with Physicians
Way and Williamson Medical Center on the west side of the Parkway Williamson
Street or Route County
Franklin TN
City State Zip Code

2. **Contact Person Available for Responses to Questions**

Scott Warwick Vice President
Name Title
MTPC, LLC scott.warwick@provisionproton.com
Company Name Email address
6450 Provision Cares Way Knoxville TN 37909
Street or Route City State Zip Code
Vice President (865) 684-2613 (865) 243-3470
Association with Owner Phone Number Fax Number

3. **Owner of the Facility, Agency or Institution**

MTPC, LLC (865) 684-2613
Name Phone Number
2095 Lakeside Centre Way Ste. 101 Knox
Street or Route County
Knoxville TN 37909
City State Zip Code

4. **Type of Ownership of Control** (See "Ownership Structure" at page 6)

A. Sole Proprietorship	_____	F. Government (State of TN or Political Subdivision)	_____
B. Partnership	_____	G. Joint Venture	_____
C. Limited Partnership	_____	H. Limited Liability Company	xx
D. Corporation (For Profit)	_____	I. Other (Specify)	_____
E. Corporation (Not-for-Profit)	_____		_____

**PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND
REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.**

5. **Name of Management/Operating Entity (If Applicable)**

Provision Proton Centers, LLC

Name

6450 Provision Cares Way

Street or Route

Knoxville

City

TN

State

Knox

County

37909

Zip Code

**PUT ALL ATTACHMENTS AT THE END OF THE APPLICATION IN ORDER AND
REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.**

6. **Legal Interest in the Site of the Institution (Check One)**

A. Ownership

D. Option to Lease

B. Option to Purchase xx

E. Other (Specify)

C. Lease of Years

**PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND
REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.**

7. **Type of Institution (Check as appropriate--more than one response may apply)**

A. Hospital (Specify)

I. Nursing Home

B. Ambulatory Surgical Treatment
Center (ASTC), Multi-Specialty

J. Outpatient Diagnostic Center

C. ASTC, Single Specialty

K. Recuperation Center

D. Home Health Agency

L. Rehabilitation Facility

E. Hospice

M. Residential Hospice

F. Mental Health Hospital

N. Non-Residential Methadone
Facility

G. Mental Health Residential

O. Birthing Center

Treatment Facility

P. Other Outpatient Facility

H. Mental Retardation Institutional
Habilitation Facility (ICF/MR)

(Specify) Proton Therapy xx

Q. Other (Specify)

8. **Purpose of Review (Check) as appropriate--more than one response may apply)**

A. New Institution xx

G. Change in Bed Complement

B. Replacement/Existing Facility

[Please note the type of change
by underlining the appropriate

C. Modification/Existing Facility

response: Increase, Decrease,
Designation, Distribution,
Conversion, Relocation]

D. Initiation of Health Care
Service as defined in TCA §
68-11-1607(4)

H. Change of Location

(Specify) Proton Therapy xx

I. Other (Specify)

E. Discontinuance of OB Services

F. Acquisition of Equipment xx

9. **Bed Complement Data**

Please indicate current and proposed distribution and certification of facility beds.

	<u>Current Beds Licensed *CON</u>	<u>Staffed Beds</u>	<u>Beds Proposed</u>	<u>TOTAL Beds at Completion</u>
A. Medical	_____	_____	_____	_____
B. Surgical	_____	_____	_____	_____
C. Long-Term Care Hospital	_____	_____	_____	_____
D. Obstetrical	_____	_____	_____	_____
E. ICU/CCU	_____	_____	_____	_____
F. Neonatal	_____	_____	_____	_____
G. Pediatric	_____	_____	_____	_____
H. Adult Psychiatric	_____	_____	_____	_____
I. Geriatric Psychiatric	_____	_____	_____	_____
J. Child/Adolescent Psychiatric	_____	_____	_____	_____
K. Rehabilitation	_____	_____	_____	_____
L. Nursing Facility (non-Medicaid Certified)	_____	_____	_____	_____
M. Nursing Facility Level 1 (Medicaid only)	_____	_____	_____	_____
N. Nursing Facility Level 2 (Medicare only)	_____	_____	_____	_____
O. Nursing Facility Level 2 (dually certified Medicaid/Medicare)	_____	_____	_____	_____
P. ICF/MR	_____	_____	_____	_____
Q. Adult Chemical Dependency	_____	_____	_____	_____
R. Child and Adolescent Chemical Dependency	_____	_____	_____	_____
S. Swing Beds	_____	_____	_____	_____
T. Mental Health Residential Treatment	_____	_____	_____	_____
U. Residential Hospice	_____	_____	_____	_____
TOTAL	_____	_____	_____	_____

*CON-Beds approved but not yet in service

10. Medicare Provider Number _____ To be requested
Certification Type _____

11. Medicaid Provider Number _____ To be requested
Certification Type _____

12. If this is a new facility, will certification be sought for Medicare and/or Medicaid? See page 4.

13. *Identify all TennCare Managed Care Organizations/Behavioral Health Organizations (MCOs/BHOs) operating in the proposed service area. Will this project involve the treatment of TennCare participants? YES If the response to this item is yes, please identify all MCOs/BHOs with which the applicant has contracted or plans to contract. See page 4.*

Discuss any out-of-network relationships in place with MCOs/BHOs in the area.

A.12. IF THIS IS A NEW FACILITY, WILL CERTIFICATION BE SOUGHT FOR MEDICARE AND/OR MEDICAID?

This new facility will seek certification from both Medicare and TennCare.

A.13. IDENTIFY ALL TENNCARE MANAGED CARE ORGANIZATIONS / BEHAVIORAL HEALTH ORGANIZATIONS (MCO'S/BHO'S) OPERATING IN THE PROPOSED SERVICE AREA. WILL THIS PROJECT INVOLVE THE TREATMENT OF TENNCARE PARTICIPANTS? Yes IF THE RESPONSE TO THIS ITEM IS YES, PLEASE IDENTIFY ALL MCO'S WITH WHICH THE APPLICANT HAS CONTRACTED OR PLANS TO CONTRACT.

DISCUSS ANY OUT-OF-NETWORK RELATIONSHIPS IN PLACE WITH MCO'S/BHO'S IN THE AREA.

The applicant will seek contracts with all TennCare and Medicaid MCO's within its primary service area and with Medicaid programs in Alabama, Kentucky, and Mississippi. Following is a list of TennCare MCO's active in Middle Tennessee at the time of this application.

Available TennCare MCO's	Applicant's Relationship
United Healthcare Community Plan	Will request contract
BlueCare	Will request contract
AMERIGROUP	Will request contract
TennCare Select	Will request contract

SECTION B: PROJECT DESCRIPTION

B.I. PROVIDE A BRIEF EXECUTIVE SUMMARY OF THE PROJECT NOT TO EXCEED TWO PAGES. TOPICS TO BE INCLUDED IN THE EXECUTIVE SUMMARY ARE A BRIEF DESCRIPTION OF PROPOSED SERVICES AND EQUIPMENT, OWNERSHIP STRUCTURE, SERVICE AREA, NEED, EXISTING RESOURCES, PROJECT COST, FUNDING, FINANCIAL FEASIBILITY AND STAFFING.

Proposed Services and Equipment - This application is for a Proton Therapy facility in Franklin, TN, to serve the Greater Middle Tennessee Area. It will be the first such facility in Middle Tennessee and only the 4th for adults in the Southeastern United States. This advanced technology treats cancerous tumors with proton beams, rather than photon beams that are emitted by linear accelerators. Proton Therapy's unique advantages for certain patients are discussed in the Need summary below. The Proton Therapy center will use an accelerator-based treatment system manufactured by Sumitomo Heavy Industries, Ltd. an international Proton Therapy equipment manufacturer with an installed base of facilities.

The project will enable Middle Tennessee to join national and regional leaders in the use of this technology, such as the Massachusetts General Hospital (MGH), the University of Pennsylvania, the University of Texas / M.D. Anderson program at Houston and the Provision Center for Proton Therapy (PCPT) in East Tennessee. Only fourteen such facilities are now operational and all but PCPT are located distant from Tennessee patients. Thirteen other facilities are under construction including St. Jude Children's Research Hospital and Emory University in Atlanta; but no others are close to Tennessee.

Ownership Structure - The applicant is an LLC that currently has three non-profit, tax-exempt members, Provision Trust, Inc. (48%), Scott Hamilton CARES Foundation, Inc. (26%) and Provision Cares Foundation, Inc. (26%). Provision Trust, Inc. is the controlling member of the Provision Center for Proton Therapy in Knoxville and will leverage their knowledge and experience in the development of this facility. The Scott Hamilton CARES Foundation, Inc. is also cooperating in the development of this facility which will be part of the Scott Hamilton Cancer Alliance. Participation in this project, and membership in MTPC, LLC, will also be offered to tertiary hospital partners and other providers committed to oncology research and treatment. The LLC will be governed by a Board that reflects ownership, clinical partnerships, and the community. The facility will be managed by MTPC, LLC executive management with the initial support and assistance of Provision Proton Centers, LLC.

Service Area - The primary service area (PSA) will cover 38 Tennessee counties in the middle third of the State, extending through the west through the highland rim counties of Stewart, Houston, Humphreys, Perry and Wayne counties and on the east through the Cumberland Plateau counties of Clay, Overton, Putnam, White, Van Buren, Grundy, and Franklin. The North and South borders are defined by the respective Alabama and Kentucky state lines. These 38 primary service area counties are within 2 hours drive time and within 100 miles of Franklin, TN. This PSA will have 2.7 million residents in CY2020 (a population equal to 39% of Tennessee's entire population). It is projected that 60% of the Proton Therapy Center's referrals will come from within this primary service area.

The secondary service area is projected to extend approximately three hours' drive time west to Memphis, TN, north to Louisville, KY and south to Birmingham, AL. An estimated 40% of the project's patients will come from this more distant area and beyond, reflecting the experience of PCPT in East Tennessee.

The combined primary and secondary service areas are projected to have more than 9.5 million residents in CY2020.

Need - The goal of all radiation treatment is to deliver enough ionizing radiation into a tumor to destroy cancerous cells, while minimizing damage to healthy tissue as the beams enter and exit the tumor ("collateral damage"). This collateral damage causes, or intensifies, undesirable short and long-term side effects. These include but are not limited to nausea, diarrhea, and bleeding as well as, permanently damaged tissues outside the tumor site, and increased risk of secondary malignant tumors from the radiation itself.

Proton therapy is the most advanced radiation treatment modality available that minimizes collateral damage. It delivers extremely high radiation doses within the tumor while limiting radiation continuing beyond the defined tumor volume. Proton therapy greatly reduces patient side effects and substantially

reduces risks of subsequent problems such as secondary malignant tumors and loss of function in surrounding tissues. Proton therapy is considered especially promising for treatment of children's tumors, because the escaping radiation in other technologies can have significant adverse impacts on children's rapidly growing organs. Clinical Studies from MGH have demonstrated significant reductions in vision and hearing loss, growth retardation and secondary malignancies in comparison to conventional radiation therapy treatments. Demand is growing for Proton Therapy treatment for head and neck cancers because of the reductions of the significant toxicities associated with conventional radiation treatment allowing patients to complete their treatment without interruptions or medical interventions. There is also increasing demand for Proton Therapy in brain, breast, liver, lung, prostate and other cancers due to the decrease in toxicities from treatment.

Demand for proton therapy continues to grow as the clinical evidence continues to distinguish its short and long term benefits over existing technologies. Middle Tennessee patients who could benefit from this unique type of treatment need timely access within a reasonable drive time. This facility will provide that access, and will complement other cancer care resources in the Primary Service Area, without requiring the State's healthcare providers to finance a new capital expenditure or assume additional risk. The project will meet an estimated 15% - 20% of the primary service area need for proton therapy, and will convert only 6% of primary service area radiation therapy patients to proton therapy patients.

Additional proton treatment facilities are also needed nationally so that larger numbers of patients can be enrolled in clinical research studies to allow for more cancer indications to be treated with Proton Therapy. The Provision Center for Proton Therapy in Knoxville and its research partner, the Center for Biomedical Research, have developed and implemented regional and national research studies for this purpose. The proposed Middle Tennessee center will participate in the existing clinical studies and become part of a state and nationwide network of proton therapy facilities that work together to conduct clinical research using proton technology.

Existing Resources - The closest existing proton therapy centers are east in Knoxville, TN; west in St. Louis, MO, north in Chicago, IL; and south in Jacksonville, FL. Because of the increasing recognition of the clinical value of proton therapy, centers are under construction in Memphis, TN (St. Jude Children's Research Hospital) and Atlanta, GA (Emory University) The center at St. Jude will be limited to pediatric patients and the center in Atlanta will be many hours' drive from Middle Tennessee patients and does not offer practical access for them.

Project Cost, Funding, Feasibility, Staffing - Proton facilities require a large capital investment, due to the need for a high-energy accelerator to accelerate the protons to high energies and significant radiation shielding with exacting structural specifications in large areas of the facility. This project's estimated cost for CON purposes is \$105,727,789 of which \$91,719,789 are capital costs. The project will be funded through the sale of tax-exempt bonds that will be issued by the Williamson County Industrial Development Board and underwritten by Deutsche Bank. The applicant projects a positive cash flow beginning in 2020.

Utilization will require two full operating shifts, 7 am to 11 pm, Monday through Friday. The two shifts combined will require employing 53 FTE's, including Radiation Oncologists, Medical Physicists, Medical Dosimetrists, Registered Nurses, Radiation Therapists, and support staff. The Medical Director, to be selected after CON approval is granted, will be a board-certified Radiation Oncologist trained in the use of proton therapy. The medical staff will be open to all radiation oncologists appropriately trained and credentialed in proton therapy.

B.II. PROVIDE A DETAILED NARRATIVE OF THE PROJECT BY ADDRESSING THE FOLLOWING ITEMS AS THEY RELATE TO THE PROPOSAL.

B.II.A. DESCRIBE THE CONSTRUCTION, MODIFICATION AND/OR RENOVATION OF THE FACILITY (EXCLUSIVE OF MAJOR MEDICAL EQUIPMENT COVERED BY T.C.A. 68-11-1601 *et seq.*) INCLUDING SQUARE FOOTAGE, MAJOR OPERATIONAL AREAS, ROOM CONFIGURATION, ETC.

1. Location

The Scott Hamilton Proton Center (“SHPC”) will be located on Carothers Parkway in Franklin, approximately 2 minutes’ drive east of I-65 at Exit 65 in central Williamson County. The site is on the east side of the Parkway, between its intersection with Physicians Way and the Williamson Medical Center (WMC) hospital campus on the west side of the Parkway. Tennessee Oncology, the largest Medical Oncology practice in Tennessee is located on the WMC campus. Immediately adjacent to the North side of the WMC campus is the Vanderbilt-Ingram Cancer Center at Franklin that provides conventional radiation therapy services. WMC provides inpatient & outpatient hospital services including comprehensive surgical, laboratory, and imaging services in addition to other major physician practice groups.

2. Design and Space Requirements

For convenient reference, the site plan, floor plan, and space listing for the facility are provided at the end of this subsection, as well as in Attachments B.III and B.IV at the end of the application.

The Proton Therapy center will occupy a dedicated new building of approximately 36,083 square feet. New construction is necessary because the shielding and weight-bearing requirements of proton treatment facilities exceed normal building specifications.

For example, the proton treatment system proposed here is a cyclotron-based system that requires significant concrete shielding walls, up to 10 feet thick, around the proton beam generation area, the proton beam paths, the patient treatment rooms where the beams are directed into tumors, and the corridors providing access to all those areas. The building foundation must be able to support weights up to 220 tons. Thousands of feet of electrical conduit are required. Structural specifications resemble those of an industrial facility. It will take up to two years to grade and build this facility.

SHPC's preliminary design has two floors. The first floor contains patient care areas including the proton treatment vaults and operations support spaces. The second floor houses staff offices, support spaces, and electrical and mechanical equipment. The floors are connected by an elevator and by stairs. A complete space listing is provided with the floor plan at the end of this response.

Patients will enter and register on the first floor where they will have a large lobby that will include a convenience center for drinks and snacks. On the left side of the center, the Nursing area consists of 7 exam rooms for patient consultations and weekly "on-treatment-visits" with their physician while under treatment. Patients under treatment are taken to changing rooms in front of the treatment vaults to prepare for treatment before entering to receive their treatment.

The proton treatment system is housed in three shielded rooms or "vaults", accessible through heavily shielded access doors and supported by control rooms. Each of the vaults has a proton control room nearby. One vault houses an accelerator that accelerates the proton beam. Its beam is directed into three adjoining vaults. One of those vaults is a "fixed-beam treatment room" (the patient lies on a table with the beam directed into the tumor from a fixed position). The second and third vaults are "gantry treatment rooms" (a gantry rotates the beam delivery mechanism around the patient table to treat from multiple angles).

The right side of the first floor has a specialized CT area with simulation, control, and workrooms that send patient data to the proton treatment planning areas on the second floor. The floor also contains several offices, utility, and storage rooms.

The second floor of the building contains research, physics and treatment planning spaces, conference rooms, a large meeting space, medical and facility staff offices and support rooms, an IT room, storage rooms, and mechanical/electrical rooms.

SHPC's proximity to the Williamson Medical Center campus across the Parkway will provide easy access to PET/CT, MRI and other imaging capabilities that will be available to support patient treatment planning and evaluation at SHPC.

3. Operating Hours and Development Schedule

Fully operational, the facility will treat patients up to 16 hours a day, 7 am to 11 pm, five days (80 hours) per week. If the project receives final CON approval by June 1, 2015, it is projected to open by

January 2, 2019. Calendar years 2019 and 2020 are projected to be its first two full calendar years of operation.

4. Ownership of the Applicant

The applicant is MTPC, LLC, a limited liability company that is in the process of seeking designation as a not for profit public charity. The applicant's three members are Provision Trust, Inc. (48%), Scott Hamilton CARES Foundation, Inc. (26%) and Provision CARES Foundation, Inc. (26%). Provision Trust, Inc. is the controlling member of the Provision Center for Proton Therapy in Knoxville and brings its experience successfully developing and operating that facility to this project. Scott Hamilton CARES Foundation, Inc. is cooperating in the development of this project which will be a member of the Scott Hamilton Cancer Alliance along with the Provision Center for Proton Therapy and others.

Medical direction will be provided by a board-certified radiation oncologist that is appropriately trained in the use of proton therapy. The proton therapy center will be located in close proximity to the Williamson Medical Center in Franklin, TN and other oncology providers to allow for the greatest integration of the center with the existing oncology community and facilities. Additionally, the proton therapy center will be an open center where all duly qualified and credentialed physicians will have the ability to refer and treat their patients that they have determined would benefit from Proton Therapy. The applicant will pursue clinical and research partnerships with all local hospital and healthcare provider(s) and physician groups that offer comprehensive oncology programs and are committed to oncology research. To the extent permitted by law and in furtherance of the applicant's clinical and research objectives, clinical partners will be offered membership interests in the applicant.

Control of the applicant LLC will mirror its ownership structure. Its governance will be representative of the community. The applicant LLC will be governed by a board of directors selected by current and future charitable LLC members with input from its clinical partner(s).

5. Development and Management

The applicant LLC will own both the building and equipment. The facility will be developed and managed by Provision entities that successfully developed the Provision Center for Proton Therapy in Knoxville. The Provision team brings substantial, hands-on experience regarding the cost-effective development and operation of a proton therapy center. A draft management services agreement is provided in the attachments.

6. Capital Costs

A proton therapy facility requires major capital costs to construct and equip. For example, some of the concrete walls will be up to ten feet thick. The foundation must be able to support weights of up to 220 tons. Thousands of feet of electrical conduit are required. The structure will resemble an industrial facility in many respects. The construction of the accelerator and proton beam vaults will be especially costly.

HSDA rules require that the project cost for CON purposes include not only actual capital expenditures, but also "fair market values" for the shell space being leased in the building (if applicable), and the operational expenses of multi-year equipment maintenance contracts. The total project cost for CON purposes is estimated at \$103,711,714. Its components are shown in the Project Cost Chart in Section C(II) of the application and discussed in Section C(II)1. Of that amount, \$89,703,714 is estimated to be the actual front-end capital expenditure (excluding the operational expenses of service contracts).

7. Financing

The project's capital cost as well as any required reserve funds and allowable expenses will be fully funded through the issuance of tax-exempt bonds. The issuing authority will be the Industrial Development Board of Williamson County. Deutsche Bank Securities, Inc. will be the underwriter and/or placement agent for the bond issuance. Deutsche Bank has experience with such issuances insofar as they acted as underwriter and placement agent for the issuance of tax-exempt revenue bonds for the Provision Center for Proton Therapy in Knoxville.

Copies of the Industrial Development Board's preliminary resolution authorizing the issuance and Deutsche Bank Securities' conditional agreement to proceed with the issuance are provided collectively in Attachment C, Economic Feasibility -2.



[illegible]

Architectural floor plan of the Fermilab Main Ring tunnel area. The plan shows the circular path of the Main Ring tunnel, with various rooms and equipment labeled. Key areas include the Cyclotron room, Cyclotron cooling room, Energy selection system, Beam transport system, Horizontal Beam Treatment Room, 1st and 2nd Super treatment rooms, and various support rooms like the Control room, Maintenance room, and Storage room. Dimensions are provided for various sections of the tunnel and rooms.

Scott Hamilton Proton Center

1st Floor – Medical Office Space



APPLICANTS WITH HOSPITAL PROJECTS (CONSTRUCTION COST IN EXCESS OF \$5 MILLION) AND OTHER FACILITY PROJECTS (CONSTRUCTION COST IN EXCESS OF \$2 MILLION) SHOULD COMPLETE THE SQUARE FOOTAGE AND COSTS PER SQUARE FOOTAGE CHART.

UTILIZING THE ATTACHED CHART, APPLICANTS WITH HOSPITAL PROJECTS SHOULD COMPLETE PARTS A-E BY IDENTIFYING, AS APPLICABLE, NURSING UNITS, ANCILLARY AREAS, AND SUPPORT AREAS AFFECTED BY THIS PROJECT. PROVIDE THE LOCATION OF THE UNIT/SERVICE WITHIN THE EXISTING FACILITY ALONG WITH CURRENT SQUARE FOOTAGE, WHERE, IF ANY, THE UNIT/SERVICE WILL RELOCATE TEMPORARILY DURING CONSTRUCTION AND RENOVATION, AND THEN THE LOCATION OF THE UNIT/SERVICE WITH PROPOSED SQUARE FOOTAGE. THE TOTAL COST PER SQUARE FOOT SHOULD PROVIDE A BREAKOUT BETWEEN NEW CONSTRUCTION AND RENOVATION COST PER SQUARE FOOT. OTHER FACILITY PROJECTS NEED ONLY COMPLETE PARTS B-E.

See Attachment B.II.A.

PLEASE ALSO DISCUSS AND JUSTIFY THE COST PER SQUARE FOOT FOR THIS PROJECT.

This facility will be unique to the Middle Tennessee area. Its building structure is very different from structures housing other types of megavoltage radiation therapy units. The nearest two facilities that are similar to this project are the Provision Center for Proton Therapy in Knoxville and the Proton Therapy center in Memphis that is currently under construction.

The construction cost estimate in this application was based on designs and construction information provided by the Provision Center for Proton Therapy and Sumitomo Heavy Industries, Ltd., along with the Knoxville-based equipment manufacturer ProNova Solutions, LLC which is developing and equipping proton therapy centers at Oxford University in England, Singapore and Tianjin, China. The costs projected in this application were estimated by a licensed contractor and architect who were involved in the design and construction of the proton therapy facility in Knoxville. They estimate an average construction cost of \$481 PSF (which includes certain types of site work requiring heavy equipment). The construction cost of non-shielded and patient care areas, which excludes the shielded vaults, is \$175 PSF. The shielded vault areas are almost a third of the facility and will cost \$1,150 PSF. Following is a comparison of square foot costs for the proton therapy center approved in Knoxville as well as the projected costs from the unimplemented St. Jude Children's Research Hospital Proton Therapy CON application in Memphis.

<u>CON #</u>	<u>Provider</u>	<u>Construction Cost</u>	<u>SF</u>	<u>Cost/SF</u>
1002-010A	The Proton Therapy Center			
	Knox County	\$35,880,630	87,005 SF	\$412
1105-01A	St. Jude Children's Research Hospital			
	Shelby County	\$46,122,963	139,336 SF	\$331
<hr/>				
Proposed	Scott Hamilton Proton Center	\$17,370,127	36,083 SF	\$481

IF THE PROJECT INVOLVES NONE OF THE ABOVE, DESCRIBE THE DEVELOPMENT OF THE PROPOSAL.

Not applicable.

B.II.B. IDENTIFY THE NUMBER AND TYPE OF BEDS INCREASED, DECREASED, CONVERTED, RELOCATED, DESIGNATED, AND/OR REDISTRIBUTED BY THIS APPLICATION. DESCRIBE THE REASONS FOR CHANGE IN BED ALLOCATIONS AND DESCRIBE THE IMPACT THE BED CHANGE WILL HAVE ON EXISTING SERVICES.

Not applicable to an outpatient facility.

B.II.C. AS THE APPLICANT, DESCRIBE YOUR NEED TO PROVIDE THE FOLLOWING HEALTH CARE SERVICES (IF APPLICABLE TO THIS APPLICATION):

1. ADULT PSYCHIATRIC SERVICES
2. ALCOHOL AND DRUG TREATMENT ADOLESCENTS >28 DAYS
3. BIRTHING CENTER
4. BURN UNITS
5. CARDIAC CATHETERIZATION SERVICES
6. CHILD AND ADOLESCENT PSYCHIATRIC SERVICES
7. EXTRACORPOREAL LITHOTRIPSY
8. HOME HEALTH SERVICES
9. HOSPICE SERVICES
10. RESIDENTIAL HOSPICE
11. ICF/MR SERVICES
12. LONG TERM CARE SERVICES
13. MAGNETIC RESONANCE IMAGING (MRI)
14. MENTAL HEALTH RESIDENTIAL TREATMENT
15. NEONATAL INTENSIVE CARE UNIT
16. NON-RESIDENTIAL METHADONE TREATMENT CENTERS
17. OPEN HEART SURGERY
18. POSITIVE EMISSION TOMOGRAPHY
19. RADIATION THERAPY/LINEAR ACCELERATOR
20. REHABILITATION SERVICES
21. SWING BEDS

1. How Proton Therapy Helps Cancer Patients

Proton therapy is the most advanced form of radiation treatment available. It differs significantly from radiation delivered by linear accelerators, cyber-knives, and gamma knives. Most such devices treat tumors by directing photon or gamma ray beams into the tumor site, where they deposit high doses of ionizing radiation that destroy cancerous cells. But photon beams also radiate healthy tissues as the beam enters the body, hits the tumor and exits the body. Recent developments in radiation therapy technology such as IMRT or VMAT and new types of external beam units have improved providers' ability to shape and target photon beams for better tumor site coverage. Unfortunately, these new techniques can sometimes result in greater "collateral" radiation damage to healthy tissue than older forms of conventional radiation treatments.

The collateral radiation damage can create several short and long-term side effects. The undesirable side effects can include nausea, diarrhea, bleeding, increased fatigue and, potentially, loss of function in the irradiated tissue. Conventional radiation therapy also creates a significant latent risk of secondary malignant tumors as early as five years after treatment. And where the tumor is near sensitive organs, concern about collateral damage can restrict the physician from delivering high enough dosages to

ensure tumor destruction. The constant challenge to the radiation oncology team is to “conform and confine” by reaching all areas of the tumor with sufficient dosage to destroy the tumor, while containing all radiation within the tumor so that potentially harmful radiation to healthy tissue is limited.

The proton therapy equipment that is proposed in this project helps minimize the aforementioned short and long-term side effects. It delivers protons, rather than photons, to the tumor location without delivering significant radiation doses in the body after depositing the radiation dose in the tumor. Protons are much heavier than photons and distribute their energy slowly until they reach a point called the Bragg Peak. The Bragg Peak is a physical characteristic of protons that results in the majority of the radiation dose being deposited in the physician defined tumor volume. Once this dose is delivered to the tumor, the radiation stops and does not continue to radiate healthy tissues beyond the tumor as do photons. The proton radiation dose range can be controlled with great precision by adjusting the energy of the protons. This results in the ability to deliver high radiation dosages in the tumor without measurable radiation exiting into healthy tissue beyond the tumor.

These unique proton properties offer a significant clinical advantage. When high radiation dosages are needed to destroy a tumor it can be accomplished without harming critically important tissues outside the tumor. Examples include certain cancers of the eye, brain, breast, esophagus, head & neck, liver, lung, pancreatic, prostate, pediatric, and others cancers adjacent to critical organs and structures.

Proton therapy provides special clinical benefits to pediatric patients. Children are more susceptible to radiation injury because their organs are growing rapidly. Proton therapy allows children’s cancers to be treated with less of the collateral damage that causes bodily dysfunctions, impaired cognitive performance, tissue atrophy, and subsequent new tumors. The significance of this clinical value is evidenced by the request and approval of a CON for the St. Jude Children’s Research Hospital Proton Therapy center in Memphis. This center is planned to open in July of 2016. In the meantime, Proton Therapy pediatric research is being performed by St. Jude Children’s Research Hospital through collaboration with the University of Florida Health Proton Therapy Institute.

Due to the precise delivery of radiation to the tumor and the reduction in side effects, Proton Therapy allows the increased utilization of hypofractionation. Hypofractionation is the delivery of far fewer, larger doses of radiation to achieve the same curative effect as conventional radiation therapy delivered in smaller doses over an extended period of time. This is significant in that it significantly reduces the overall cost of proton therapy treatment while also allowing patients to return to their

activities weeks earlier than normal, resulting in improved work productivity for patients and the community.

The medical experience and literature documenting the superiority of proton therapy over conventional radiation therapy for various types of tumors and patients continues to grow and develop. Below is a brief summary of key findings from several recent studies regarding proton therapy:

- Five-year clinical outcomes for prostate cancer patients with image-guided proton therapy included extremely high efficacy, minimal physician-assessed toxicity, and excellent patient reported outcomes.¹
- Proton beam radiation therapy for partial breast radiation produced excellent ipsilateral breast recurrence-free survival with minimal toxicity. Cosmetic results may be improved over those reported with photon-based techniques due to reduced breast tissue exposure with proton beam.²
- A Mayo Clinic meta-analysis of 41 sinus and nasal cavity cancer observational studies noted better loco-regional control, disease-free survival, and overall survival in all patients who were treated with charged particle therapy (protons), compared with those receiving photon therapy, at either 5 years or at longest duration of treatment, or both periods.³
- Gastrostomy tubes (abdominal feeding tubes) decrease by over 50% with proton therapy in comparison to conventional radiation therapy during the treatment of oropharyngeal cancer patients.⁴

¹ Mendenhall, Nancy P., Bradford S. Hoppe, Romaine C. Nichols, et al. 2014. "Five-Year Outcomes from 3 Prospective Trials of Image-Guided Proton Therapy for Prostate Cancer." *International Journal of Radiation Oncology*Biophysics* 88 (3): 596–602. doi:10.1016/j.ijrobp.2013.11.007.

² Bush, David A., Sharon Do, Sharon Lum, Carlos Garberoglio, et al. 2014. "Partial Breast Radiation Therapy With Proton Beam: 5-Year Results With Cosmetic Outcomes." *International Journal of Radiation Oncology*Biophysics* 90 (3): 501–5. doi:10.1016/j.ijrobp.2014.05.1308.

³ Patel, Samir H, Zhen Wang, William W Wong, Mohammad Hassan Murad, et al. 2014. "Charged Particle Therapy versus Photon Therapy for Paranasal Sinus and Nasal Cavity Malignant Diseases: A Systematic Review and Meta-Analysis." *The Lancet Oncology*, June. doi:10.1016/S1470-2045(14)70268-2.

⁴ Patel, Samir H, Zhen Wang, William W Wong, Mohammad Hassan Murad, Courtney R Buckey, Khaled Mohammed, Fares Alahdab, et al. 2014. "Charged Particle Therapy versus Photon Therapy for Paranasal Sinus and Nasal Cavity Malignant Diseases: A Systematic Review and Meta-Analysis." *The Lancet Oncology*, June. doi:10.1016/S1470-2045(14)70268-2.

- Higher doses of proton radiation can be delivered to lung tumors with a lower risk of esophagitis and pneumonitis in comparison to conventional radiation therapy.⁵
- Proton Therapy can reduce the calculated incidence of radiogenic second cancers in prostate patients compared with IMRT. The finding was principally attributed to the ability of proton therapy to reduce the primary dose in sensitive organs near the target volume compared with IMRT.⁶
- The use of proton therapy was not associated with a significantly increased risk of secondary malignancies compared with photon therapy.⁷

2. Proton Therapy Facilities in the United States

Proton therapy is not new, experimental or investigational. In the United States the first Proton Therapy treatments were delivered in the mid-1950's by the University of California-Berkeley and followed by Harvard in the 1960's. The FDA approved Proton Therapy for cancer treatment in 1988. It was first offered as a hospital clinical service in 1990 at Loma Linda University Medical Center in California. Proton therapy is reimbursed by Medicare and by most health insurance programs in states with proton facilities, although coverages vary. There are several manufacturers that produce proton therapy equipment that are approved by the FDA. Additional manufacturers are in various stages of the development and FDA approval process, including ProNova Solutions, a Knoxville-based Proton Therapy equipment manufacturer. More than 42,000 U.S. patients, and more than 106,000 patients worldwide, have been treated with proton therapy.

⁵ Patel, Samir H, Zhen Wang, William W Wong, Mohammad Hassan Murad, Courtney R Buckey, Khaled Mohammed, Fares Alahdab, et al. 2014. "Charged Particle Therapy versus Photon Therapy for Paranasal Sinus and Nasal Cavity Malignant Diseases: A Systematic Review and Meta-Analysis." *The Lancet Oncology*, June. doi:10.1016/S1470-2045(14)70268-2.

⁶ Fontenot, Jonas D., Andrew K. Lee, et al. 2009. "Risk of Secondary Malignant Neoplasms From Proton Therapy and Intensity-Modulated X-Ray Therapy for Early-Stage Prostate Cancer." *International Journal of Radiation Oncology • Biology • Physics* 74 (2): 616–22. doi:10.1016/j.ijrobp.2009.01.001.

⁷ Chung, Christine S, Torunn I Yock, Kerrie Nelson, Yang Xu, et al. 2013. "Incidence of Second Malignancies among Patients Treated with Proton versus Photon Radiation." *International Journal of Radiation Oncology, Biology, Physics* 87 (1): 46–52. doi:10.1016/j.ijrobp.2013.04.030.

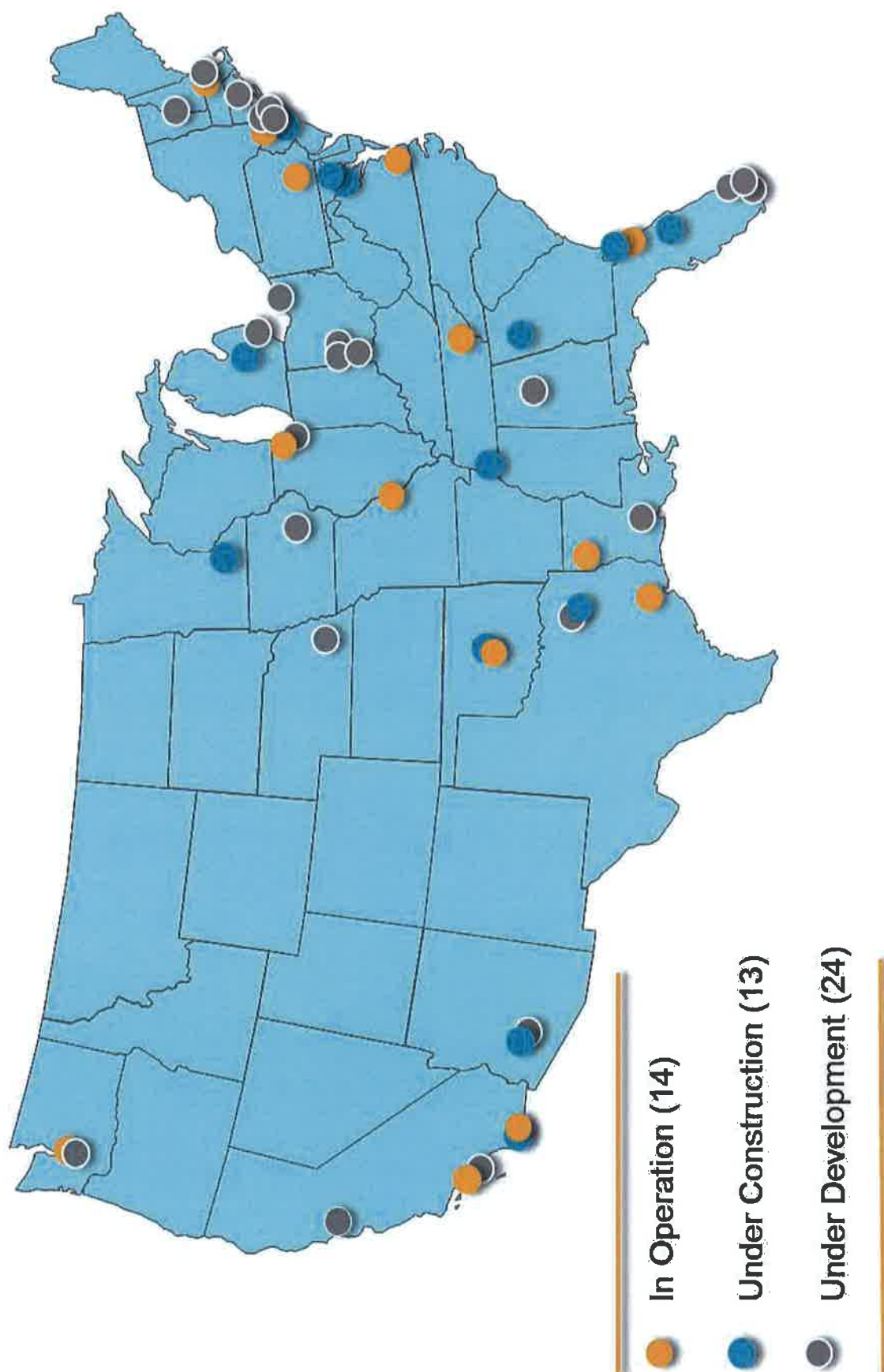
Widespread installation of proton therapy facilities for treatment and research was not financially feasible until the twenty-first century because of their unusually high capital requirements. However, as equipment prices have begun to decrease and studies continue to show the benefits of the therapy, facilities are being developed at an unprecedented rate with the nation's foremost cancer centers leading the way. In fact, the development of regional facilities is becoming more financially feasible in response to the growing demand for the service from referring physicians and patients. Ultimately, it is important for national proton therapy capacity to be increased to both meet patient demand and facilitate further research regarding the applications, efficacy and benefits of the therapy.

In the U.S., approximately twenty-seven proton therapy facilities in numerous states are operational or under construction. An additional twenty-four facilities are in feasibility planning. Facilities currently exist or are planned in twenty-six States. Most are being developed by alliances of private benefactors, universities, and providers, to help minimize the cost burdens for regional health systems. The fourteen proton therapy providers that are operational as of January 2015 are:

- Loma Linda University Medical Center, Loma Linda, CA
- Massachusetts General Hospital, in Boston, MA
- M.D. Anderson Proton Therapy Center, in Houston, TX
- University of Florida Proton Therapy Institute, in Jacksonville, FL
- ProCure Proton Therapy Center, in Oklahoma City, OK
- University of Pennsylvania / Children's Hospital of PA, in Philadelphia, PA
- CDH Proton Center, in Chicago, IL
- Hampton University Proton Therapy Institute, in Hampton, VA
- ProCure Proton Therapy Center, Somerset, NJ
- Seattle Cancer Care Alliance / ProCure Proton Therapy Center, in Seattle, WA
- Washington University Barnes-Jewish Hospital Proton Therapy Center, in St. Louis, MO
- Provision Center for Proton Therapy, in Knoxville, TN
- Scripps Proton Therapy Center, in San Diego, CA
- Willis-Knighton Proton Therapy Center, in Shreveport, LA

Exhibit One-A on the following page consists of a map showing the locations of existing and projected proton therapy providers in the United States, based on the applicant's interviews with providers, manufacturers, development consultants, and Certificate of Need applications in other States. Operational sites are shown by orange circles; sites under construction are in blue, and sites in development or planning stages are indicated by grey circles.

EXHIBIT ONE-A
PROTON THERAPY CENTERS IN THE U.S.



3. Service Void in Middle Tennessee

As illustrated in the Exhibit One-A map above, there is no proton therapy facility existing, or under active development, within most of the Southeastern United States. Proton facilities closest to Middle Tennessee are, or will be, located in East Tennessee, Georgia, and Missouri. Exhibit One-B below shows the long drive times and distances from major Middle Tennessee cities to existing proton treatment facilities or those under development in comparison to a Franklin facility.

EXHIBIT ONE-B DRIVE TIMES AND DISTANCES TO CLOSEST EXISTING AND PROPOSED PROTON THERAPY CENTERS

<u>Middle Tennessee City</u>	<u>Proton Therapy Center</u>	<u>Distance</u>	<u>Drive Time</u>
Franklin	Knoxville, TN	196 miles	2h 52 min
	Atlanta, GA	245 miles	3h 40 min
Clarksville	St. Louis, MO	265 miles	3h 55 min
	Knoxville, TN	225 miles	3h 21 min
	Franklin, TN	69 miles	1h 13 min
Murfreesboro	Atlanta, GA	216 miles	3h 12 min
	Knoxville, TN	180 miles	2h 40 min
	Franklin, TN	29 miles	0h 45 min
Nashville	Atlanta, GA	248 miles	3h 41 min
	Knoxville, TN	179 miles	2h 39 min
	Franklin, TN	22 miles	0h 26 min

Source: Google Maps

4. Service Area Definition for this Project

The Proton Therapy center in Franklin is projected to have a regional primary service area that includes 38 counties in Middle Tennessee. The primary service area is depicted in the Exhibit One-C map and Exhibit One-D county listing below. It does not duplicate any of the primary service area counties of the Provision Center for Proton Therapy in Knoxville.

The service area takes into account the experience and projections of provider teams associated with several proton therapy facilities. Based on experience at the Provision Center for Proton Therapy in Knoxville, interviews with other providers, and other CON applications, it is clear that proton centers are in high demand and are attracting approximately 25–45% of their patients from far beyond their historical primary service areas. Proton centers typically will have primary service areas with a radius of between one and two hundred miles, with significant numbers of referrals also coming from other states or regions of the U.S. as well as other countries that do not have proton therapy available locally.

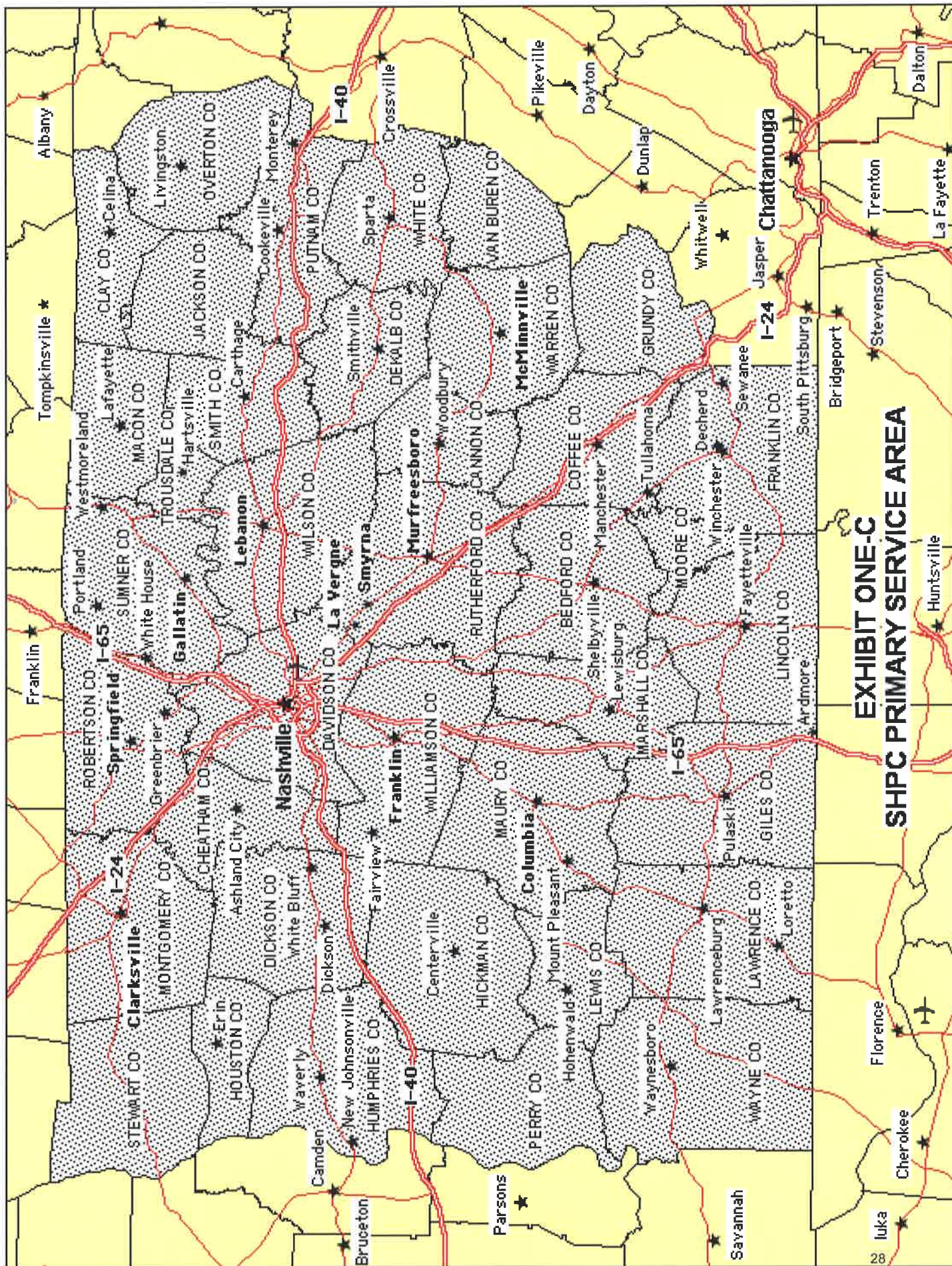
For this project the applicant used mapping sources to identify counties of Tennessee and adjoining States that were within a 2-hour drive time of Franklin, at distances up to approximately 100 miles.

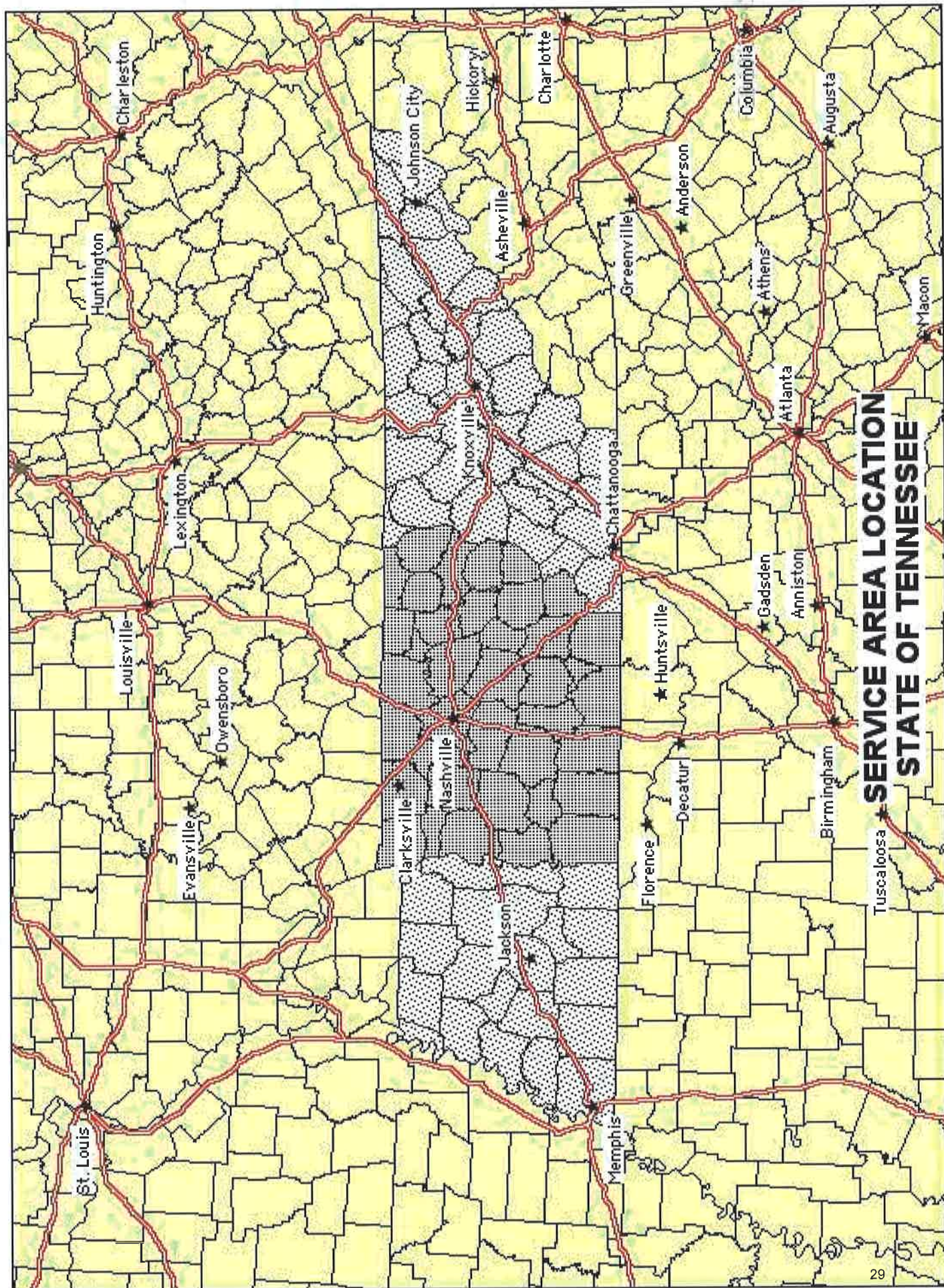
The primary service area boundaries were identified by using 1-2 hour drive times and natural geographic borders commonly utilized to identify Middle Tennessee. The western boundary was identified by using a 1.5-2 hour drive time that reaches west to the Tennessee River – the natural western geographical border for Middle Tennessee. The northern boundary utilizes the Tennessee / Kentucky state line and a 1-hour drive time for identification. Likewise the southern boundary is identified by utilizing a 1-hour drive time and the Tennessee / Alabama state line. The eastern boundary is identified by 1.5-2 hour drive times reaching to the western edge of the Cumberland Plateau the natural eastern geographical border for Middle Tennessee. These boundaries result in a geographic primary service area of 38 counties providing complete coverage of Middle Tennessee.

Exhibits One-C (County map) and One-D (County list) below show the projected primary service area that resulted from the above analysis. This area has a projected Year 2019 population of more than 2.7 million persons (equal to 39% of the total Tennessee State population in 2019). Exhibit One-E below details the demographic characteristics of the 38-county PSA.

As described in the service area narrative later in this application, this primary service area is projected to generate 60% of total patient referrals in Year Two of the project. Areas outside the primary service area, within a drive time of three-four hours, constitute a secondary service area that is projected to contribute 40% of total referrals.

This is consistent with the experience of other regional proton therapy facilities, which on average receive about 25-45% of their referrals from outside their own States.





**SERVICE AREA LOCATION
STATE OF TENNESSEE**

EXHIBIT ONE-D
COUNTIES (38) OF SHPC PRIMARY SERVICE AREA

County		State	County		State
1	Bedford	Tennessee	20	Marshall	Tennessee
2	Cannon	Tennessee	21	Maury	Tennessee
3	Cheatham	Tennessee	22	Montgomery	Tennessee
4	Clay	Tennessee	23	Moore	Tennessee
5	Coffee	Tennessee	24	Overton	Tennessee
6	Davidson	Tennessee	25	Perry	Tennessee
7	DeKalb	Tennessee	26	Putnam	Tennessee
8	Dickson	Tennessee	27	Robertson	Tennessee
9	Franklin	Tennessee	28	Rutherford	Tennessee
10	Giles	Tennessee	29	Smith	Tennessee
11	Grundy	Tennessee	30	Stewart	Tennessee
12	Hickman	Tennessee	31	Sumner	Tennessee
13	Houston	Tennessee	32	Trousdale	Tennessee
14	Humphreys	Tennessee	33	Van Buren	Tennessee
15	Jackson	Tennessee	34	Warren	Tennessee
16	Lawrence	Tennessee	35	Wayne	Tennessee
17	Lewis	Tennessee	36	White	Tennessee
18	Lincoln	Tennessee	37	Williamson	Tennessee
19	Macon	Tennessee	38	Wilson	Tennessee

5. Need for Proton Therapy in the Primary Service Area

The primary service area encompasses 38 counties in Middle Tennessee. For a uniform planning framework, the applicant queried commercial databases from Truven Health Analytics (formerly Thomson Reuters) to identify service area population, and utilized Truven's projection of the CY2014 and CY2019 & CY2020 incidence of cancer cases by county, based on Medicare files and SEER data.

Truven's case (incidence) projection provided a five-year projection from CY2014 through CY2019. The applicant applied Truven's annual projected change in each county, to project cancer cases by county in CY2019. Next, conservative step-down factors were applied to arrive at the number of area residents who were eligible for proton therapy and who would use a Franklin facility. The methodology is discussed and illustrated with data exhibits in Section C(I).6 of the application (Utilization Projections).

In summary, the total case projection was 15,206 new cancer cases in CY2019. In the step-down process, the percent of those that would receive radiation therapy was estimated at a conservative minimum of 60%. Of those receiving radiation therapy, at least 15% to 20% will be considered eligible for proton therapy. These factors were based on a 2013 study performed by Georgetown University, a 2011 Advisory Board report, a CY2007 study conducted by London-based IMS Health, and a 2005 Swedish study. The use of these step-down factors indicates that 1,369-1,825 patients in the primary service area would benefit from proton therapy.

In Year Two, CY2020, the proposed Scott Hamilton Proton Therapy Center will treat 949 patients, operating at full capacity. An estimated 60%, or 569 patients, will come from the 38-county primary service area. The patients served will be 15%-20% of the service area's total number of patients who are eligible for proton therapy and only 6% of the primary service area's projected radiation therapy patients.

B.II.D. DESCRIBE THE NEED TO CHANGE LOCATION OR REPLACE AN EXISTING FACILITY.

Not applicable.

B.II.E. DESCRIBE THE ACQUISITION OF ANY ITEM OF MAJOR MEDICAL EQUIPMENT (AS DEFINED BY THE AGENCY RULES AND THE STATUTE) WHICH EXCEEDS A COST OF \$1.5 MILLION; AND/OR IS A MAGNETIC RESONANCE IMAGING SCANNER (MRI), POSITRON EMISSION TOMOGRAPHY (PET) SCANNER, EXTRACORPOREAL LITHOTRIPTER AND/OR LINEAR ACCELERATOR BY RESPONDING TO THE FOLLOWING:

1. For fixed site major medical equipment (not replacing existing equipment):

- a. Describe the new equipment, including:**
 - 1. Total Cost (As defined by Agency Rule);**
 - 2. Expected Useful Life;**
 - 3. List of clinical applications to be provided; and**
 - 4. Documentation of FDA approval.**
- b. Provide current and proposed schedule of operations.**

2. For mobile major medical equipment:

- a. List all sites that will be served;**
- b. Provide current and/or proposed schedule of operations;**
- c. Provide the lease or contract cost;**
- d. Provide the fair market value of the equipment; and**
- e. List the owner for the equipment.**

3. Indicate applicant's legal interest in equipment (e.g., purchase, lease, etc.) In the case of equipment purchase, include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.

A chart of the projected equipment, its costs, and its maintenance contract costs, follows this page. These are maximum price quotations or estimates, which may decrease after negotiation. The applicant plans to purchase the equipment.

The four major components (excluding "other equipment") will have a useful life of five years or more. The proton therapy equipment will have a minimum useful life of 20 years. The equipment will be used to provide proton therapy planning and treatment for all clinically eligible types of cancer. The FDA letter for the major medical equipment (the cyclotron and particle accelerator) is provided in Attachment B.II.E.1. Equipment systems will operate from 7 am to 11 pm weekdays, 252 days per year, except during maintenance periods, which will be minimal.

Proton Therapy Equipment					
Modality	Cost	Service/Year	Service Yr 1	Service Yrs 2-5	CON COST
PT Eqpt (Cyclotron & Rooms)	\$47,531,450	\$0	\$589,000	\$12,099,000	\$60,219,450
Treatment Planning System	\$1,000,000	\$100,000	\$0	\$400,000	\$1,400,000
Oncology Information System	\$800,000	\$80,000	\$0	\$320,000	\$1,120,000
Simulator	\$600,000	\$60,000	\$0	\$240,000	\$840,000
Miscellaneous Equipment (Dosimetry, Gating, Other)	\$900,000	\$90,000	\$0	\$360,000	\$1,260,000
TOTAL	\$50,831,450	\$330,000	\$589,000	\$13,419,000	\$64,839,450

B.III.A. ATTACH A COPY OF THE PLOT PLAN OF THE SITE ON AN 8-1/2" X 11" SHEET OF WHITE PAPER WHICH MUST INCLUDE:

- 1. SIZE OF SITE (IN ACRES);**
- 2. LOCATION OF STRUCTURE ON THE SITE;**
- 3. LOCATION OF THE PROPOSED CONSTRUCTION; AND**
- 4. NAMES OF STREETS, ROADS OR HIGHWAYS THAT CROSS OR BORDER THE SITE.**

PLEASE NOTE THAT THE DRAWINGS DO NOT NEED TO BE DRAWN TO SCALE. PLOT PLANS ARE REQUIRED FOR ALL PROJECTS.

See Attachment B.III

B.III.B. DESCRIBE THE RELATIONSHIP OF THE SITE TO PUBLIC TRANSPORTATION ROUTES, IF ANY, AND TO ANY HIGHWAY OR MAJOR ROAD DEVELOPMENTS IN THE AREA. DESCRIBE THE ACCESSIBILITY OF THE PROPOSED SITE TO PATIENTS/CLIENTS.

The project site is on the east side of Carothers Parkway within a few minutes' drive of Exit 65 (Highway 96) on I-65 in Franklin, TN; central to the region the project will serve. Interstates and good Federal and State highways connect Franklin to all parts of the primary service area. The Exhibit One map and county listing in section B show that all 38 counties in the primary service area are within a 2-hour drive of the project site. The drive time data was obtained from Google Maps. The project site is conveniently located within thirty minutes' drive from Nashville's international airport and the location where three major interstates (I-40, I-24 and I-65) meet. Location maps are provided in Attachment C, Need-3.

B.IV. ATTACH A FLOOR PLAN DRAWING FOR THE FACILITY WHICH INCLUDES PATIENT CARE ROOMS (NOTING PRIVATE OR SEMI-PRIVATE), ANCILLARY AREAS, EQUIPMENT AREAS, ETC.

See Attachment B.IV.

IV. FOR A HOME CARE ORGANIZATION, IDENTIFY

- 1. EXISTING SERVICE AREA (BY COUNTY);**
- 2. PROPOSED SERVICE AREA (BY COUNTY);**
- 3. A PARENT OR PRIMARY SERVICE PROVIDER;**
- 4. EXISTING BRANCHES AND/OR SUB-UNITS; AND**
- 5. PROPOSED BRANCHES AND/OR SUBUNITS.**

Not applicable. The application is not for a home care organization

C(I) NEED

C(I).1. DESCRIBE THE RELATIONSHIP OF THIS PROPOSAL TO THE IMPLEMENTATION OF THE STATE HEALTH PLAN AND TENNESSEE'S HEALTH: GUIDELINES FOR GROWTH.

- A. PLEASE PROVIDE A RESPONSE TO EACH CRITERION AND STANDARD IN CON CATEGORIES THAT ARE APPLICABLE TO THE PROPOSED PROJECT. DO NOT PROVIDE RESPONSES TO GENERAL CRITERIA AND STANDARDS (PAGES 6-9) HERE.**
- B. APPLICATIONS THAT INCLUDE A CHANGE OF SITE FOR A HEALTH CARE INSTITUTION, PROVIDE A RESPONSE TO GENERAL CRITERION AND STANDARDS (4)(a-c).**

Project-Specific Review Criteria: Megavoltage Radiation Therapy Service

1. The need for megavoltage radiation therapy equipment shall be based upon the following assumptions:

- a. Each radiation therapy unit should serve a population of at least 120,000 people.**

Complies. The project will serve a primary service area with a population exceeding 2.7 million people in CY2019, the planning horizon recommended in these criteria

- b. Minimum capacity is 6,000 procedures per unit annually, serving a minimum of 300 cancer patients annually.**

Complies. The applicant projects serving 854 patients per year in the second year of service, in a two-shift operation that will deliver 25,193 annual treatments. The facility's treatment system will serve three patients simultaneously.

c. Optimal capacity is 9,984 procedures per unit annually. (Capacity is determined by assuming that 4 patients per hour X 48 hours per week X 52 weeks per year equals 9,984. The minimum capacity assumes 60% utilization of each piece of equipment. The net operational hours include allowances for equipment quality assurance procedures, warm-up time for a linear accelerator, room preparation, and other support activities.)

Complies. The project will exceed this efficiency standard. Without considering downtime for scheduled service, the facility has a maximum annual capacity of 725,760 minutes of treatment time, in three patient treatment rooms operating 16 hours per day. The applicant projects full utilization in Year Two, with a total of 854 patients receiving 25,193 treatments. This will require 523,434 minutes of time, or 72% of total capacity.

2. The need should be based upon the current year's population projected four years into the future.

Complies. The needs analysis projected primary service area demand through CY2019, four years from the current year.

3. The service area shall mean the county or counties represented by an applicant as the reasonable area to which a healthcare institution intends to provide radiation therapy services and/or in which the majority of its service recipients reside.

Complies. The project's referral assumptions were based on the planning and experience of other proton therapy providers and proton equipment manufacturers and developers, with whom the applicant consulted. These are regional resources that have been found to attract approximately 25-45% of their referrals from outside their primary service area. Patients living within a 3-hour to 4-hour drive time from a proton center typically drive in weekly, returning home or staying in lodging over each weekend during their four to eight week courses of treatment.

4. No additional megavoltage radiation therapy units shall be approved unless every existing unit in the service area has performed 6,000 or more procedures per unit annually.

Should not apply. Proton Therapy is a new service to the area and is the most advanced technology that is much needed for a referral region of more than 2.7 million residents.

5. The applicant must provide evidence that the proposed radiation therapy equipment is safe and effective for its proposed use:

- a. The USFDS shall certify the proposed equipment for clinical use.**
- b. the applicant must demonstrate that the proposed service will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and all licensing agencies' requirements.**
- c. Staffing should include a radiation oncologist, a radiation physicist, and two therapy technologists per unit.**

The FDA letter of certification is in Attachment B.II.E.1. The architect will ensure conformity to applicable standards, specifications, codes and licensure requirements, as attested in his letter in Attachment C, Economic Feasibility-1. Staffing will include the listed professionals as well as the necessary clinical and administrative support staff. The radiation oncologist who will medically supervise the service will be recruited once CON approval is granted and detailed planning can go forward. He or she will be Board-certified and trained in the use of proton therapy.

C(I).2. DESCRIBE THE RELATIONSHIP OF THIS PROJECT TO THE APPLICANT'S LONG RANGE DEVELOPMENT PLANS, IF ANY

The Applicant, MTPC, LLC, is currently an LLC with three not-for-profit, tax-exempt Members – Provision Trust, Inc. (48%), Scott Hamilton CARES Foundation, Inc. ("SHCF") (26%), and Provision CARES Foundation, Inc. (26%). Provision Trust, Inc. is the controlling member of the Provision Center for Proton Therapy in Knoxville and brings to this project years of experience successfully developing and operating that facility. Further, this project is being developed in cooperation with the Scott Hamilton CARES Foundation, Inc. (SHCF). This represents an important collaboration in developing a center that will be part of a much larger alliance aimed at better coordinating efforts in the fight against cancer.

SCHF is dedicated to improving cancer patient survivorship by supporting world-class cancer research and the highest quality patient treatment and care. The term CARES stands for Cancer Alliance for Research Education and Survivorship. SHCF is focused on all aspects of patient care in developing strong partnerships with leading institutions, cancer support groups and researchers throughout the United States to support initiatives focused on research, education and survivorship. SHCF is focused on creating synergistic alliances between granting foundations, research institutions and cancer treatment centers to better coordinate efforts in the fight against cancer. SHCF is focused on early detection, advanced diagnostics and leading-edge cancer treatment in an effort to significantly improve cure rates and quality of life.

SHCF takes an inclusive, collaborative approach seeking to partner with healthcare providers and hospitals to develop a national network of “Scott CARES Cancer & Wellness Centers” which will provide patient-centric, advanced, comprehensive, and integrated cancer patient care. Among other things, these centers will emphasize the use of advanced diagnostic imaging and treatment capabilities for diagnosis and treatment planning and advanced chemo and radiation therapy, including proton therapy.

Provision CARES Foundation, Inc. focuses on primarily three charitable areas, educational forums and wellness programs, clinical research and support for individuals and families that have incurred significant medical expenses as a result of a catastrophic medical event.

The introduction of proton therapy in Middle Tennessee and the development of a center that is open to all qualified and properly credentialed radiation oncologists, regardless of hospital affiliation, will substantially further the goals of coordinating efforts, facilitating cutting edge research and providing the most advanced therapies to improve cure rates and quality of life for cancer patients. The proton therapy center that is the subject of this application is expected to be a critical component in the network of cancer care providers under the umbrella of the Scott Hamilton Cancer Alliance.

C(I).3. IDENTIFY THE PROPOSED SERVICE AREA AND JUSTIFY THE REASONABLENESS OF THAT PROPOSED AREA. SUBMIT A COUNTY-LEVEL MAP INCLUDING THE STATE OF TENNESSEE CLEARLY MARKED TO REFLECT THE SERVICE AREA. PLEASE SUBMIT THE MAP ON A 8-1/2” X 11” SHEET OF WHITE PAPER MARKED ONLY WITH INK DETECTABLE BY A STANDARD PHOTOCOPIER (I.E., NO HIGHLIGHTERS, PENCILS, ETC.).

A service area map and a map showing the location of the service area within the State of Tennessee are provided as Attachments C, Need--3 at the end of the application.

The proton therapy centers developed so far have large regional service areas. CON materials reviewed by the applicant from other locations generally projected service areas extending 100 to 250 miles from the facility. The project’s referral assumptions were based on the planning and experience of other proton therapy providers and proton equipment manufacturers and developers with whom the applicant consulted. Proton therapy centers are regional resources that have been found to attract approximately 25-45% of their referrals from outside their primary service area. The applicant's research in 2014 identified no proton therapy facility open or planned in Middle Tennessee. The closest existing sites to Middle Tennessee are in Knoxville, and St. Louis, Missouri. The closest sites identified as under construction are in Memphis and Atlanta. The center in Memphis will be limited to children. Despite the

addition of centers in Knoxville and Atlanta there is still a significant void of service in the Southeastern United States. It is reasonable to assume that this project will be used by residents of this underserved region, who are accessible to the Nashville area.

For this project, the applicant used mapping sources to identify counties of Middle Tennessee and adjoining areas that were within a 2-hour drive time of Franklin, at distances up to approximately 100 miles.

The primary service area boundaries were identified by using 1-2 hour drive times and natural geographic borders commonly utilized to identify Middle Tennessee. The western boundary was identified by using a 1.5-2 hour drive time that reaches west to the Tennessee River – the natural western geographical border for Middle Tennessee. The northern boundary utilizes the Tennessee / Kentucky state line and a 1-hour drive time for identification. Likewise the southern boundary is identified by utilizing a 1-hour drive time and the Tennessee / Alabama state line. The eastern boundary is identified by 1.5-2 hour drive times reaching to the western edge of the Cumberland Plateau the natural eastern geographical border for Middle Tennessee. These boundaries result in a primary service area of 38 counties providing complete coverage of Middle Tennessee.

Exhibits One-D (County map) and One-E (County list) in section B.II.C. Above (Project Need section) show the projected primary service area that resulted from the above analysis. Exhibit Three in the next response below shows that area, has a projected Year 2019 population of approximately 2,700,000 persons (equal to 42% of the total Tennessee State population that year). This primary service area is projected to generate 60% of total patient referrals in Year Two of the project.

Areas outside the primary service area, within a drive time of three hours, constitute a secondary service area that is projected to contribute 40% of total referrals. The two areas combined are projected to have a population of more than 9,429,505 persons in CY2019. Based on current plans of proton equipment manufacturers who were interviewed by the applicant, a Franklin proton therapy facility would be the closest such facility for most of the residents of this entire area.

For a service of this magnitude, concerned with life-threatening illness, it is reasonable to assume drive times of 2 hours and 3.0 hours for the primary and secondary service areas. This would not be a daily commute. Patients referred to proton therapy sites from remote locations typically stay near the

service throughout their weekday treatments, and commute home on weekends. Courses of treatment typically range from 20 to 42 treatments per case, over a period of four to eight weeks.

C.I.4.A DESCRIBE THE DEMOGRAPHICS OF THE POPULATION TO BE SERVED BY THIS PROPOSAL.

The applicant obtained demographic data from the Tennessee Department of Health population projections from May of 2013, the 2010 US Census, US Census QuickFacts, and the State of Tennessee TennCare Bureau.

Exhibit Three, below, shows that the primary service area, which includes 38 counties in Middle Tennessee, has a projected Year 2020 population of 2,735,974 persons. The area projected population in 2015 was 13.2% elderly (65+ years); and in 2019 it is projected to be 14.9% elderly. The total population will increase by 5.5% from CY2015 to CY2019 and the elderly population will increase by as much as 13.5%.

Cancer rates increase steeply in elderly segments of the population. The aging of the service area by 2019 is a major factor in the projected increase of cancer incidence in these counties between 2015 and 2019.

EXHIBIT THREE - DEMOGRAPHIC CHARACTERISTICS OF PRIMARY SERVICE AREA
Scott Hamilton Proton Center
2015-2019

County	Demographic Characteristics													
	Median Age - 2010 Census	Total Population 2015	Total Population 2019	Total Population % Change 2015 - 2019	Total Population Age 65+ 2015	% of Population Age 65+ 2015	Total Population Age 65+ 2019	% of Population Age 65+ 2019	Age 65+ Population Change 2015 - 2019	Median Household Income	TennCare Enrollees	Percent of 2014 Population Enrolled in TennCare	Persons Below Poverty Level 2014	Persons Below Poverty Level as % of Population US Census
Bedford	36.4	48,099	51,495	7.1%	7,002	14.6%	7,778	16.2%	11.1%	\$45,901	11,025	22.9%	9,620	20.0%
Cannon	41.4	14,218	14,631	2.9%	2,550	17.9%	2,742	19.3%	7.5%	\$40,689	2,643	18.6%	2,531	17.8%
Cheatham	39.3	40,088	40,965	2.2%	5,115	12.8%	6,076	15.2%	18.8%	\$52,446	6,453	16.1%	5,532	13.8%
Clay	45.1	7,681	7,684	0.0%	1,733	22.6%	1,792	23.3%	3.4%	\$29,727	1,965	25.6%	1,582	20.6%
Coffee	39.7	54,817	57,619	5.1%	7,938	14.5%	7,261	13.2%	-8.5%	\$37,618	11,343	20.7%	11,457	20.9%
Davidson	33.9	663,151	688,318	3.8%	77,086	11.6%	88,812	13.4%	15.2%	\$47,335	124,103	18.7%	122,683	18.5%
DeKalb	41.0	18,996	19,172	0.9%	3,448	18.2%	3,765	19.8%	9.2%	\$37,482	4,629	24.4%	3,609	19.0%
Dickson	38.7	51,127	52,248	2.2%	7,110	13.9%	7,795	15.2%	9.6%	\$44,318	9,368	18.3%	7,874	15.4%
Franklin	41.3	41,391	42,408	2.5%	7,479	18.1%	7,402	17.9%	-1.0%	\$42,904	6,675	16.1%	6,250	15.1%
Giles	42.1	29,293	29,282	0.0%	5,547	18.9%	6,036	20.6%	8.8%	\$38,495	5,312	18.1%	5,712	19.5%
Grundy	41.4	13,322	13,303	-0.1%	2,693	20.2%	2,837	21.3%	5.3%	\$26,814	4,443	33.4%	3,957	29.7%
Hickman	40.0	24,465	24,784	1.3%	4,076	16.7%	4,751	19.4%	16.6%	\$39,581	5,462	22.3%	4,257	17.4%
Houston	41.8	8,413	8,449	0.4%	1,671	19.9%	1,791	21.3%	7.2%	\$35,271	1,692	20.1%	1,977	23.5%
Humphreys	41.9	18,519	18,581	0.3%	3,656	19.7%	3,864	20.9%	5.7%	\$42,846	3,605	19.5%	2,574	13.9%
Jackson	44.7	11,383	11,520	1.2%	2,385	21.0%	2,593	22.8%	8.7%	\$33,386	2,581	22.7%	2,516	22.1%
Lawrence	39.7	42,373	42,373	0.0%	7,628	18.0%	8,140	19.2%	6.7%	\$37,368	8,905	21.0%	7,670	18.1%
Lewis	41.2	12,112	12,259	1.2%	2,269	18.7%	2,545	21.0%	12.2%	\$34,397	2,567	21.2%	2,410	19.9%
Lincoln	41.8	34,624	36,059	4.1%	5,104	14.7%	4,979	14.4%	-2.4%	\$41,571	6,405	18.5%	5,644	16.3%
Macon	38.7	23,419	24,366	4.0%	3,775	16.1%	4,275	18.3%	13.2%	\$35,306	6,061	25.9%	4,965	21.2%
Marshall	38.9	31,413	32,322	2.9%	4,970	15.8%	5,668	18.0%	14.0%	\$42,291	5,575	17.7%	5,089	16.2%
Maury	38.4	82,526	83,485	1.2%	12,774	15.5%	14,550	17.6%	13.9%	\$45,336	15,237	18.5%	12,709	15.4%
Montgomery	30.0	191,068	203,460	6.5%	16,969	8.9%	19,759	10.3%	16.4%	\$49,617	25,741	13.5%	31,335	16.4%
Moore	43.3	6,364	6,415	0.8%	1,267	19.9%	1,257	19.8%	-0.8%	\$46,170	781	12.3%	840	13.2%
Overton	41.6	22,593	23,104	2.3%	4,364	19.3%	4,633	20.5%	6.2%	\$34,604	4,561	20.2%	5,061	22.4%
Perry	43.1	8,025	8,103	1.0%	1,768	22.0%	1,953	24.3%	10.5%	\$32,845	1,887	23.5%	1,693	21.1%
Putnam	35.9	78,416	83,992	7.1%	11,684	14.9%	12,498	15.9%	7.0%	\$33,709	14,591	18.6%	20,780	26.5%
Robertson	37.6	71,437	75,312	5.4%	8,312	11.6%	9,689	13.6%	16.6%	\$52,792	11,427	16.0%	9,287	13.0%
Rutherford	32.2	302,237	338,904	12.1%	28,650	9.5%	34,874	11.5%	21.7%	\$55,401	38,869	12.9%	39,291	13.0%
Smith	39.9	19,771	20,468	3.5%	3,134	15.9%	3,496	17.7%	11.6%	\$42,383	3,762	19.0%	3,836	19.4%
Stewart	42.8	13,659	14,027	2.7%	2,549	18.7%	2,785	20.4%	9.3%	\$39,781	2,596	19.0%	2,732	20.0%
Sumner	38.6	175,054	186,146	6.3%	26,272	15.0%	30,856	17.6%	17.4%	\$55,509	24,135	13.8%	18,206	10.4%
Trousdale	39.5	8,275	8,667	4.7%	1,275	15.4%	1,431	17.3%	12.2%	\$43,034	1,761	21.3%	1,125	13.6%
Van Buren	44.5	5,433	5,488	1.0%	1,149	21.1%	1,286	23.7%	11.9%	\$33,547	1,185	21.8%	1,222	22.5%
Warren	39.3	40,662	41,362	1.7%	6,823	16.8%	7,339	18.0%	7.6%	\$34,641	9,600	23.6%	8,742	21.5%
Wayne	40.9	16,815	16,691	-0.7%	3,063	18.2%	3,286	19.5%	7.3%	\$33,198	2,972	17.7%	3,397	20.2%
White	42.0	27,132	28,275	4.2%	5,132	18.9%	5,423	20.0%	5.7%	\$34,474	6,176	22.8%	5,399	19.9%
Williamson	38.5	207,872	228,670	10.0%	24,219	11.7%	28,889	13.9%	19.3%	\$89,779	9,214	4.4%	11,849	5.7%
Wilson	39.3	126,472	135,567	7.2%	18,939	15.0%	22,683	17.9%	19.8%	\$60,390	6,345	5.0%	12,900	10.2%
Tennessee PSA	39.9	2,592,715	2,735,974	5.5%	341,578	13.2%	387,589	14.9%	13.5%	\$42,183	411,652	15.9%	408,311	15.7%
State of Tennessee	38.0	6,649,438	6,894,997	3.7%	1,012,937	15.2%	1,134,565	17.1%	12.0%	\$44,298	1,241,028	18.7%	1,170,301	17.6%

Sources: TDH Population Projections, May 2013; U.S. 2010 Census & QuickFacts
TennCare Bureau April 2014. PSA data is unweighted average or total of county data.

C(I).4.B. DESCRIBE THE SPECIAL NEEDS OF THE SERVICE AREA POPULATION, INCLUDING HEALTH DISPARITIES, THE ACCESSIBILITY TO CONSUMERS, PARTICULARLY THE ELDERLY, WOMEN, RACIAL AND ETHNIC MINORITIES, AND LOW-INCOME GROUPS. DOCUMENT HOW THE BUSINESS PLANS OF THE FACILITY WILL TAKE INTO CONSIDERATION THE SPECIAL NEEDS OF THE SERVICE AREA POPULATION.

Cancer for the most part is a disease of the elderly and the area population is aging. The project will greatly improve physical accessibility to a new care option for all of the above groups. SHPC will accept referrals of all of the above listed groups and will be accessible to TennCare patients.

C(I).5. DESCRIBE THE EXISTING OR CERTIFIED SERVICES, INCLUDING APPROVED BUT UNIMPLEMENTED CON'S, OF SIMILAR INSTITUTIONS IN THE SERVICE AREA. INCLUDE UTILIZATION AND/OR OCCUPANCY TRENDS FOR EACH OF THE MOST RECENT THREE YEARS OF DATA AVAILABLE FOR THIS TYPE OF PROJECT. BE CERTAIN TO LIST EACH INSTITUTION AND ITS UTILIZATION AND/OR OCCUPANCY INDIVIDUALLY. INPATIENT BED PROJECTS MUST INCLUDE THE FOLLOWING DATA: ADMISSIONS OR DISCHARGES, PATIENT DAYS, AND OCCUPANCY. OTHER PROJECTS SHOULD USE THE MOST APPROPRIATE MEASURES, E.G., CASES, PROCEDURES, ETC.

There are no existing or approved proton therapy facilities in this primary service area (PSA) of 38 counties that will have 2,700,000 residents in CY2019. The facilities treating patients with conventional radiation therapy are not comparable to proton therapy facilities even though both are megavoltage radiation therapy for purposes of requiring CON approval..

There is one operational proton therapy center in the state, the Provision Center for Proton Therapy in Knoxville, that opened in January 2014. In 2014, it provided 8,846 treatments and projects to provide 22,785 treatments in 2015.

There is one approved but unimplemented proton therapy CON at St. Jude Children's Hospital in Memphis. St. Jude projects to provide 2,944 treatments in 2017, 3,818 in 2018, and 4,577 treatments in 2019, with all treatments to St. Jude pediatric patients. The actual and projected utilization trends of both of these institutions are listed below in Exhibit four. This project described a primary service area encompassing nine States. It is limited to treating pediatric patients. Its utilization is heavily tied to children enrolled in research studies. It is a national resource that was not intended to meet other types of patient needs in West Tennessee.

EXHIBIT 4
STATE OF TENNESSEE
PROTON THERAPY CENTER UTILIZATION

<u>Implemented CONs</u>	<u>Year</u>	<u>Number of Treatments</u>
The Proton Therapy Center, LLC (dba Provision Center for Proton Therapy)	2014 (actual)	8,846
	2015 (projected)	22,785
	2016 (projected)	26,400
<u>Unimplemented CONs</u>	<u>Year</u>	<u>Number of Treatments</u>
St. Jude Children's Research Hospital	2017 (projected)	2,944
	2018 (projected)	3,818
	2019 (projected)	4,577

C.I.6. PROVIDE APPLICABLE UTILIZATION AND/OR OCCUPANCY STATISTICS FOR YOUR INSTITUTION FOR EACH OF THE PAST THREE (3) YEARS AND THE PROJECTED ANNUAL UTILIZATION FOR EACH OF THE TWO (2) YEARS FOLLOWING COMPLETION OF THE PROJECT. ADDITIONALLY, PROVIDE THE DETAILS REGARDING THE METHODOLOGY USED TO PROJECT UTILIZATION. THE METHODOLOGY MUST INCLUDE DETAILED CALCULATIONS OR DOCUMENTATION FROM REFERRAL SOURCES, AND IDENTIFICATION OF ALL ASSUMPTIONS.

The primary service area encompasses 38 counties in middle Tennessee region. The applicant queried commercial databases from Truven Health Analytics to identify service area population (Exhibit Three), and projections of the CY2019 and CY2020 incidence of cancer cases by county, based on published data from the National Cancer Institute (Exhibit Five).

Truven Health Analytics, formerly known as Thomson Healthcare Division, has specialized in healthcare data analysis for more than 30 years. Truven Health Analytics provides comprehensive databases, performs market analyses, and provides research services to the healthcare industry, worldwide.

Truven's case (incidence) projection provides a five-year projection from CY2014 through CY2019. The growth rate of cancer cases during the five-year period, CY2014 - CY2019, has been extrapolated to project cancer cases by county in CY2020 (year two after project completion).

Very conservative step-down factors were applied to arrive at the number of area residents who were eligible for proton therapy and who would use a Franklin facility. The factors used are based on a series of published analyses regarding the number of proton therapy patients in defined areas. The following table is a summary of estimates for proton therapy need as a percent of cancer cases in the five studies analyzed. The most important parameters used are (1) the percentage of radiation therapy patients among total cancer incidence ([A] = 60%) and (2) the percentage of patients eligible for proton therapy among all radiation therapy patients ([B] = 15-20%).

%	[A] Radiation Therapy as % Total Cancer Incidence	[B] Proton Therapy as % Radiation Therapy	[C] = [A]x[B] Proton Therapy as % Total Cancer Incidence
Swedish study (2005)	51	15	8
Netherlands study (2005)	69	16	11
IMS Health (2007)	55*	46*	25*
Advisory Board (2011)	42	47	20
Georgetown (2013)	76	25	19
Averaged	59	30	17
Used in Step-down	60	15-20	9-12

* Projection for CY2020

According to these studies, radiation therapy patients account for an average of 59% of the total cancer incidence ([A] in table above), which confirms the 60% suggested by the American Society for Radiation Oncology (ASTRO). Among the radiation therapy patients, an average of 30% are eligible for proton therapy ([B], table above). Therefore, this analysis estimates the needs for proton therapy in the proposed service area based upon a set of conservative percentages ([A] = 60% and [B] = 15-20%).

In summary, the total case projection in the primary service area is 15,206 cases in Year One, CY 2019. In the step-down process, the percent of those that would receive radiation therapy was estimated at approximately 60%, or 9,124 patients. Of those appropriate for radiation therapy, at least 15-20% will be considered eligible for proton therapy. The use of these step-down factors indicates that 1,369-1,825 patients in the primary service area would benefit from proton therapy.

Based on the projected utilization of capacity of the proposed proton therapy center, the market share of radiation and proton therapy patients in the primary service area are estimated below for CY2019 and CY2020. In Year One, CY2019, SHPC will treat 549 patients, operating at 45% of capacity. An estimated 60%, or 317 patients, will come from the 38-county primary service area. This is only 3.5% of the primary service area's projected 9,124 radiation therapy patients. It is approximately 17.4% - 23.2% of the primary service area patients who are eligible for proton therapy. Similar step-down process is presented in Exhibit Five-B for Year Two, CY 2020.

Please see Exhibits Five-A, Five-B, and Five-C on the following pages. Exhibit Five-A shows Truven Health Analytics' projection of cancer cases (incidence) in the primary service area. Exhibit Five-B shows the step-down analysis described above in this response, which identifies this project's patient population in Year One and Year Two. Exhibit Five-C displays the project's anticipated case mix by type of cancer, the range of treatments per type of patient (average of 30 over four to eight weeks), the typical minutes required (turnaround) between patients, and the annual treatment minutes. Below the table is the calculation of project capacity (available minutes of treatment time) and project operating efficiency (45% in CY2019 and 80% in CY2020).

EXHIBIT FIVE-A
SCOTT HAMILTON PROTON CENTER
PRIMARY SERVICE AREA CANCER INCIDENCE CY2014 - CY2020

County in Primary Service Area	State	2014 Cases	2019 Cases	Percent Growth 2014-2019	Annual Increase %	2020 Cases
Bedford County	TN	271	294	8%	2%	299
Cannon County	TN	81	87	8%	2%	89
Cheatham County	TN	201	227	13%	3%	233
Clay County	TN	40	42	5%	1%	42
Coffee County	TN	380	407	7%	1%	413
Davidson County	TN	2,978	3,432	15%	3%	3,537
DeKalb County	TN	128	140	10%	2%	143
Dickson County	TN	282	311	10%	2%	317
Franklin County	TN	264	278	5%	1%	281
Giles County	TN	211	219	4%	1%	221
Grundy County	TN	94	100	7%	1%	101
Hickman County	TN	141	149	5%	1%	150
Houston County	TN	64	68	7%	1%	69
Humphreys County	TN	128	133	4%	1%	134
Jackson County	TN	70	74	5%	1%	75
Lawrence County	TN	311	329	6%	1%	333
Lewis County	TN	66	67	1%	0%	67
Lincoln County	TN	247	262	6%	1%	266
Macon County	TN	121	131	8%	2%	134
Marshall County	TN	185	204	10%	2%	208
Maury County	TN	412	447	9%	2%	455
Montgomery County	TN	861	1,041	21%	4%	1,084
Moore County	TN	25	26	4%	1%	26
Overton County	TN	135	144	7%	1%	146
Perry County	TN	58	60	5%	1%	61
Putnam County	TN	529	572	8%	2%	581
Robertson County	TN	357	394	10%	2%	402
Rutherford County	TN	1,253	1,492	19%	4%	1,549
Smith County	TN	108	116	8%	2%	118
Stewart County	TN	102	111	8%	2%	113
Sumner County	TN	933	1,065	14%	3%	1,095
Trousdale County	TN	40	43	7%	1%	43
Van Buren County	TN	27	31	12%	2%	32
Warren County	TN	267	284	7%	1%	288
Wayne County	TN	124	131	6%	1%	133
White County	TN	204	217	7%	1%	220
Williamson County	TN	1,118	1,361	22%	4%	1,421
Wilson County	TN	608	714	17%	3%	739
TOTAL		13,425	15,206	13%	3%	15,617

EXHIBIT FIVE-B
PROJECTION OF AREA NEED FOR PROTON THERAPY AND MARKET SHARE
SCOTT HAMILTON PROTON CENTER PRIMARY SERVICE AREA
(38 COUNTIES IN CY2019 AND CY2020)

STEP	PROJECTIONS	CY2019	CY2020
1	TOTAL PRIMARY SERVICE AREA CASES (EXHIBIT FIVE-A)	15,206	15,617
2	PERCENT APPROPRIATE FOR RADIATION THERAPY	60%	
3	CASES APPROPRIATE FOR RADIATION THERAPY (RT)	9,124	9,370
4	PERCENT APPROPRIATE FOR REFFERAL TO PROTON THERAPY	15-20%	
5	CASES APPROPRIATE FOR PROTON THERAPY	1,369-1,825	1,406-1,874
6	CASE CAPACITY OF SHPC (UTILIZATION OF CAPACITY)	549 (46%)	854 (72%)
7	PERCENT OF TPTC CASES FROM PRIMARY SERVICE AREA	60%	
8	SHPC CASES FROM PRIMARY SERVICE AREA	329	512
9	SHPC MARKET SHARE OF PRIMARY SERVICE AREA PROTON THERAPY CASES IN STEP 5	17.4%-23.2%	30.4%-40.5%
10	SHPC MARKET SHARE OF PRIMARY SERVICE AREA RADIATION THERAPY CASES IN STEP 3	3.6%	5.5%

EXHIBIT FIVE - C
SCOTT HAMILTON PROTON CENTER
PROJECTED UTILIZATION - CY 2020

Case Mix		Annual Patients	Projected Treatments Per Patient	Annual Treatments	Treatments Minutes Per Patient	Annual Treatment Minutes
Breast	9.0%	77	33	2,536	21	53,264
Prostate	50.0%	427	29	12,383	18	222,894
Brain	10.0%	85	28	2,391	21	50,215
Lung	5.0%	43	33	1,409	25	35,228
Head & Neck	6.0%	51	33	1,691	25	42,273
Other	20.0%	171	28	4,782	25	119,560
Totals	100.0%	854	31	25,193	135	523,434

C(II)1. PROVIDE THE COST OF THE PROJECT BY COMPLETING THE PROJECT COSTS CHART ON THE FOLLOWING PAGE. JUSTIFY THE COST OF THE PROJECT.

- **ALL PROJECTS SHOULD HAVE A PROJECT COST OF AT LEAST \$3,000 ON LINE F (MINIMUM CON FILING FEE). CON FILING FEE SHOULD BE CALCULATED ON LINE D.**

- **THE COST OF ANY LEASE (BUILDING, LAND, AND/OR EQUIPMENT) SHOULD BE BASED ON FAIR MARKET VALUE OR THE TOTAL AMOUNT OF THE LEASE PAYMENTS OVER THE INITIAL TERM OF THE LEASE, WHICHEVER IS GREATER. NOTE: THIS APPLIES TO ALL EQUIPMENT LEASES INCLUDING BY PROCEDURE OR "PER CLICK" ARRANGEMENTS. THE METHODOLOGY USED TO DETERMINE THE TOTAL LEASE COST FOR A "PER CLICK" ARRANGEMENT MUST INCLUDE, AT A MINIMUM, THE PROJECTED PROCEDURES, THE "PER CLICK" RATE AND THE TERM OF THE LEASE.**

- **THE COST FOR FIXED AND MOVEABLE EQUIPMENT INCLUDES, BUT IS NOT NECESSARILY LIMITED TO, MAINTENANCE AGREEMENTS COVERING THE EXPECTED USEFUL LIFE OF THE EQUIPMENT; FEDERAL, STATE, AND LOCAL TAXES AND OTHER GOVERNMENT ASSESSMENTS; AND INSTALLATION CHARGES, EXCLUDING CAPITAL EXPENDITURES FOR PHYSICAL PLANT RENOVATION OR IN-WALL SHIELDING, WHICH SHOULD BE INCLUDED UNDER CONSTRUCTION COSTS OR INCORPORATED IN A FACILITY LEASE.**

- **FOR PROJECTS THAT INCLUDE NEW CONSTRUCTION, MODIFICATION, AND/OR RENOVATION; DOCUMENTATION MUST BE PROVIDED FROM A CONTRACTOR AND/OR ARCHITECT THAT SUPPORT THE ESTIMATED CONSTRUCTION COSTS.**

The architect's letter supporting the construction cost estimate is provided in Attachment C, Economic Feasibility--1. On the Project Costs Chart, following this response:

Line A.1, A&E fees, were estimated by the project architect for both the developer's and the applicant's building design costs.

Line A.2, legal, administrative, and consultant fees, include a contingency for expenses of an administrative appeals hearing.

Line A.3, site acquisition cost.. project will include approximately 51% of the 11.6 acres in the purchase contract. This represents \$3,750,000 of the \$7,326,792 purchase price. The remaining acreage will be used for other purposes not part of the project.

Line A.4, site preparation cost.

Line A.5, construction cost, was calculated by area. Patient care and staff areas were estimated at \$175 PSF; mechanical/electrical areas at \$175 PSF; and the vaults (shielded rooms, corridors, and beam transport spaces) at \$1,150 PSF. The overall construction cost averages \$481 PSF.

Line A.6, contingency, was estimated by the contractor at 7% of the construction costs shown in line A.5.

Line A.7 includes both fixed and moveable equipment costs. Vendor quotations for major medical equipment are provided in Attachment B.II.E.3.

Line A.9 is the major medical equipment service contract cost in Years 1-5 (not all of Year One maintenance is under warranty). The service contract vendor quotes are provided in Attachment B.II.E.3.

Line C.1, interim financing, was estimated by the Provision financial team based on their experience financing the Provision Center for Proton Therapy in Knoxville.

Line C.2, underwriting costs, was estimated by the Provision financial team based on their experience financing the Provision Center for Proton Therapy in Knoxville.

Line C.3, reserve for one year's debt service, was estimated by the Provision financial team based on their experience financing the Provision Center for Proton Therapy in Knoxville.

PROJECTS COST CHART - SCOTT HAMILTON PROTON CENTER

A. Construction and equipment acquired by purchase:

1. Architectural and Engineering Fees	\$789,651
2. Legal, Administrative, Consultant Fees (Excl CON Filing)	\$25,000
3. Acquisition of Site	\$3,750,000
4. Preparation of Site	\$1,221,150
5. Construction Cost	\$17,306,081
6. Contingency Fund	\$1,214,046
7. Fixed Equipment (PT)	\$50,831,450
8. Moveable Equipment (List all equipment over \$50,000)	\$0
9. Other (Specify) Maintenance (PT)	\$14,008,000

B. Acquisition by gift, donation, or lease:

1. Facility (inclusive of building and land)	\$0
2. Building only	0
3. Land only	0
4. Equipment (Specify)	0
5. Other (Specify)	0

C. Financing Costs and Fees:

1. Interim Financing	5,690,199
2. Underwriting Costs	1,577,212
3. Reserve for One Year's Debt Service	9,270,000
4. Other (Specify)	0

**D. Estimated Project Cost
(A+B+C)**

\$105,682,789

E. CON Filing Fee

\$45,000

F. Total Estimated Project Cost (D+E)

\$105,727,789

Applicant & Developer's Capital Costs

\$91,719,789

C(II).2. IDENTIFY THE FUNDING SOURCES FOR THIS PROJECT.

a. PLEASE CHECK THE APPLICABLE ITEM(S) BELOW AND BRIEFLY SUMMARIZE HOW THE PROJECT WILL BE FINANCED. (DOCUMENTATION FOR THE TYPE OF FUNDING MUST BE INSERTED AT THE END OF THE APPLICATION, IN THE CORRECT ALPHANUMERIC ORDER AND IDENTIFIED AS ATTACHMENT C, ECONOMIC FEASIBILITY--2).

☐ **A. Commercial Loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;**

☒ **B. Tax-Exempt Bonds--copy of preliminary resolution or a letter from the issuing authority, stating favorable contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;**

☐ **C. General Obligation Bonds--Copy of resolution from issuing authority or minutes from the appropriate meeting;**

☐ **D. Grants--Notification of Intent form for grant application or notice of grant award;**

☐ **E. Cash Reserves--Appropriate documentation from Chief Financial Officer; or**

☐ **F. Other--Identify and document funding from all sources.**

The project's capital cost will be funded by the issuance of tax-exempt bonds. The Williamson County Industrial Development Board has issued a preliminary resolution authorizing the issuance of up to \$110,000,000 of tax-exempt bonds for this project and Deutsche Bank, the underwriter and placement agent for the bond issuance for the Provision Center for Proton Therapy, has conditionally agreed to underwrite and/or place the tax-exempt bonds for this project.

Written documentation of the availability of this funding is provided in Attachment C, Economic Feasibility--2.

C(II).3. DISCUSS AND DOCUMENT THE REASONABLENESS OF THE PROPOSED PROJECT COSTS. IF APPLICABLE, COMPARE THE COST PER SQUARE FOOT OF CONSTRUCTION TO SIMILAR PROJECTS RECENTLY APPROVED BY THE HSDA.

This facility will be unique to Middle Tennessee. It has no precedent in the Primary Service Area. Its building structure is very different from structures housing other types of megavoltage radiation therapy units. The nearest proton therapy facility was constructed in Knoxville. A second facility is being constructed in Memphis, due to be completed in 2016. The applicant has not identified other published sources of historical construction costs for operational centers outside of the facility in Knoxville.

The construction cost estimate in this application was based on designs and construction information provided by the Provision Center for Proton Therapy in Knoxville, Sumitomo Heavy Industries, Ltd., and ProNova Solutions, LLC. The costs projected in this application were estimated by a licensed contractor and architect who were involved in the design construction of the proton therapy facility in Knoxville. They estimate an average construction cost of \$481 per GSF (which includes certain types of site work requiring heavy equipment). The construction cost of non-shielded areas such as mechanical and patient care areas (excluding shielded vaults) will be \$175 PSF. The shielded vault areas are almost half of the facility and will cost \$1,150 PSF. Following is a comparison of square foot costs for the proton therapy facility constructed in Knoxville, the projected costs outlined in the CON application submitted by St. Jude Children's Research Hospital for the pediatric Proton Therapy facility in Memphis and the costs for the proposed project.

<u>CON #</u>	<u>Provider</u>	<u>Construction Cost</u>	<u>SF</u>	<u>Cost/SF</u>
1002-010A	The Proton Therapy Center, LLC. Knox County	\$35,880,630	87,005 SF	\$407
1105-01A	St. Jude Children's Research Hospital Shelby County	\$46,122,963	139,336 SF	\$331
Proposed	Scott Hamilton Proton Center Williamson County	\$17,370,127	36,083 SF	\$481

C(II).4. COMPLETE HISTORICAL AND PROJECTED DATA CHARTS ON THE FOLLOWING TWO PAGES--DO NOT MODIFY THE CHARTS PROVIDED OR SUBMIT CHART SUBSTITUTIONS. HISTORICAL DATA CHART REPRESENTS REVENUE AND EXPENSE INFORMATION FOR THE LAST THREE (3) YEARS FOR WHICH COMPLETE DATA IS AVAILABLE FOR THE INSTITUTION. PROJECTED DATA CHART REQUESTS INFORMATION FOR THE TWO YEARS FOLLOWING COMPLETION OF THIS PROPOSAL. PROJECTED DATA CHART SHOULD INCLUDE REVENUE AND EXPENSE PROJECTIONS FOR THE PROPOSAL ONLY (I.E., IF THE APPLICATION IS FOR ADDITIONAL BEDS, INCLUDE ANTICIPATED REVENUE FROM THE PROPOSED BEDS ONLY, NOT FROM ALL BEDS IN THE FACILITY).

The Historical Data Chart is not applicable. See the following page for the Projected Data Chart, with notes where applicable.

PROJECTED DATA CHART-- SCOTT HAMILTON PROTON CENTER

Give information for the two (2) years following the completion of this proposal.

The fiscal year begins in January.

		CY 2019	CY 2020
	Patients	549	854
A. Utilization Data	Treatments	16,196	25,193
B. Revenue from Services to Patients			
1. Inpatient Services		\$	\$
2. Outpatient Services		87,063,885	135,295,618
3. Emergency Services			
4. Other Operating Revenue (Specify)			
	Gross Operating Revenue	\$ 87,063,885	\$ 135,295,618
C. Deductions for Operating Revenue			
1. Contractual Adjustments		\$ 65,297,916	\$ 101,471,715
2. Provision for Charity Care		544,149	845,598
3. Provisions for Bad Debt		544,149	845,598
	Total Deductions	\$ 66,386,214	\$ 103,162,911
NET OPERATING REVENUE		\$ 20,677,671	\$ 32,132,707
D. Operating Expenses			
1. Salaries and Wages		\$ 5,206,078	\$ 5,900,222
2. Physicians Salaries and Wages			
3. Supplies		1,318,699	2,049,234
4. Taxes			
5. Depreciation		5,483,145	5,483,145
6. Rent			
7. Interest, other than Capital		180,000	120,000
8. Management Fees			
a. Fees to Affiliates		1,851,991	2,882,944
b. Fees to Non-Affiliates			
9. Other Expenses (Specify)		2,709,820	5,379,227
	Utilities, IT, Professional Fees, Medical Director Fees, Annual Equipment Maintenance		
	Total Operating Expenses	\$ 16,749,733	\$ 21,814,772
E. Other Revenue (Expenses) -- Net (Specify)		\$	\$
NET OPERATING INCOME (LOSS)		\$ 3,927,938	\$ 10,317,935
F. Capital Expenditures			
1. Retirement of Principal		\$ 2,849,334	\$ 3,025,075
2. Interest		6,325,970	6,150,229
	Total Capital Expenditures	\$ 9,175,304	\$ 9,175,304
NET OPERATING INCOME (LOSS)			
LESS CAPITAL EXPENDITURES		\$ -5,247,366	\$ 1,142,631
		\$ -2,398,032	\$ 4,167,705

C(II).5. PLEASE IDENTIFY THE PROJECT'S AVERAGE GROSS CHARGE, AVERAGE DEDUCTION FROM OPERATING REVENUE, AND AVERAGE NET CHARGE.

AVERAGE CHARGE, DEDUCTIONS, AND NET CHARGES		
	2019	2020
Patients	549	854
Treatments	16,196	25,193
Average Gross Charge Per Patient	\$158,586	\$158,426
Average Gross Charge Per Treatment	\$5,376	\$5,370
Average Deduction Per Patient	\$120,922	\$120,800
Average Deduction Per Treatment	\$4,099	\$4,095
Average Net Charge (Net Operating Income) Per Patient	\$37,664	\$37,626
Average Net Charge (Net Operating Income) Per Treatment	\$1,277	\$1,275
Avg Net Charge (Net Operating Income) Per Patient After Capital Expenditures	\$7,155	\$12,082
Avg Net Charge (Net Operating Income) Per Patient After Capital Expenditures	\$243	\$410

C(II).6.A. PLEASE PROVIDE THE CURRENT AND PROPOSED CHARGE SCHEDULES FOR THE PROPOSAL. DISCUSS ANY ADJUSTMENT TO CURRENT CHARGES THAT WILL RESULT FROM THE IMPLEMENTATION OF THE PROPOSAL. ADDITIONALLY, DESCRIBE THE ANTICIPATED REVENUE FROM THE PROPOSED PROJECT AND THE IMPACT ON EXISTING PATIENT CHARGES.

There is no current charge schedule for this facility. The proposed charges are shown in the Frequent Charges Chart following the response to C(II).6.B below.

C(II).6.B. COMPARE THE PROPOSED CHARGES TO THOSE OF SIMILAR FACILITIES IN THE SERVICE AREA/ADJOINING SERVICE AREAS, OR TO PROPOSED CHARGES OF PROJECTS RECENTLY APPROVED BY THE HSDA. IF APPLICABLE, COMPARE THE PROJECTED CHARGES OF THE PROJECT TO THE CURRENT MEDICARE ALLOWABLE FEE SCHEDULE BY COMMON PROCEDURE TERMINOLOGY (CPT) CODE(S).

Comparative local charges are not available because there is not a proton therapy center in the service area. There is one existing proton therapy center in an adjoining service area. The Provision Center for Proton Therapy opened in January 2014. In their first year of operation their average gross charge was \$5,352.60. St. Jude Children's Research Hospital in Memphis projects a gross charge of \$4,032 per treatment in 2017. Following this page is a chart of projected gross charges for CPT codes associated with this service. The Medicare data used for this purpose is derived from the Medicare Physician Fee Schedule released in 2014 by Cahaba Government Benefit Administrators, LLC, the Medicare Administrative Contractor for Tennessee, Alabama, and Georgia.

SHPC FREQUENT CHARGES			
CPT HCPCS Code	Description	2015 Medicare Allowable Technical*	Gross Charges
77014	CT Guidance for Placement of RT Fields	\$107.74	\$215.48
77263	Treatment Planning, Complex	\$157.22	\$314.44
77280	Simple Simulation	\$245.72	\$491.44
77290	Complex Simulation	\$463.57	\$927.14
77295	Three-Dimensional Radiotherapy Plan	\$451.40	\$902.80
77300	Basic Dose Calculation	\$58.56	\$117.12
77301	Intensity Modulated Treatment Planning	\$1,763.71	\$3,527.42
77334	Treatment Device, Complex	\$140.50	\$281.00
77370	Special Physics Consultation	\$104.46	\$208.92
77336	Continuing Medical Physics Consultation	\$68.76	\$137.52
77421	Stereoscopic X-ray guidance for localization of target volume	\$68.45	\$136.90
77427	Radiation Treatment Management	\$176.28	\$352.56
77470	Special Treatment Procedure	\$146.01	\$292.02
77523	Proton Treatment, Intermediate	\$1,021.30	\$2,042.60
99204	New Office Visit	\$154.90	\$309.80
99213	Followup Visit	\$68.23	\$136.46

* Medicare Physician Fee Schedule for Tennessee published by
Cahaba Government Benefit Administrators, LLC. The Medicare
Administrative Contractor for Tennessee

C(II).7. DISCUSS HOW PROJECTED UTILIZATION RATES WILL BE SUFFICIENT TO MAINTAIN COST-EFFECTIVENESS.

The proton therapy center is projected to operate in Year Two at 72% efficiency which results in a cost-effective operation. Due to an extended ramp-up period associated with accepting and commissioning the proton treatment rooms in sequential order the center will operate at 80% efficiency in Year Three.

C(II).8. DISCUSS HOW FINANCIAL VIABILITY WILL BE ENSURED WITHIN TWO YEARS; AND DEMONSTRATE THE AVAILABILITY OF SUFFICIENT CASH FLOW UNTIL FINANCIAL VIABILITY IS MAINTAINED

The applicant projects a positive cash flow in the first and subsequent years. The financing model provides for reserve accounts that can be accessed to assure that cash flow will be adequate to maintain viability.

C(II).9. DISCUSS THE PROJECT'S PARTICIPATION IN STATE AND FEDERAL REVENUE PROGRAMS, INCLUDING A DESCRIPTION OF THE EXTENT TO WHICH MEDICARE, TENNCARE/MEDICAID, AND MEDICALLY INDIGENT PATIENTS WILL BE SERVED BY THE PROJECT. IN ADDITION, REPORT THE ESTIMATED DOLLAR AMOUNT OF REVENUE AND PERCENTAGE OF TOTAL PROJECT REVENUE ANTICIPATED FROM EACH OF TENNCARE, MEDICARE, OR OTHER STATE AND FEDERAL SOURCES FOR THE PROPOSAL'S FIRST YEAR OF OPERATION.

The facility is committed to contract with TennCare MCO's active in its Tennessee service area, and with Medicaid programs in the other sectors of its service area such as Kentucky, Alabama, and Mississippi.

In Year One, SHPC projects the following Medicare and TennCare/Medicaid gross charges and payer mix:

	<u>Medicare Program</u>	<u>Medicaid Program</u>
Gross Revenues	\$56,591,525	\$4,353,194
% of Total Gross Revenues	65%	5%

C(II).10. PROVIDE COPIES OF THE BALANCE SHEET AND INCOME STATEMENT FROM THE MOST RECENT REPORTING PERIOD OF THE INSTITUTION, AND THE MOST RECENT AUDITED FINANCIAL STATEMENTS WITH ACCOMPANYING NOTES, IF APPLICABLE. FOR NEW PROJECTS, PROVIDE FINANCIAL INFORMATION FOR THE CORPORATION, PARTNERSHIP, OR PRINCIPAL PARTIES INVOLVED WITH THE PROJECT. COPIES MUST BE INSERTED AT THE END OF THE APPLICATION, IN THE CORRECT ALPHANUMERIC ORDER AND LABELED AS ATTACHMENT C, ECONOMIC FEASIBILITY--10.

They are in Attachment C, Economic Feasibility--10.

C(II).11. DESCRIBE ALL ALTERNATIVES TO THIS PROJECT WHICH WERE CONSIDERED AND DISCUSS THE ADVANTAGES AND DISADVANTAGES OF EACH ALTERNATIVE, INCLUDING BUT NOT LIMITED TO:

A. A DISCUSSION REGARDING THE AVAILABILITY OF LESS COSTLY, MORE EFFECTIVE, AND/OR MORE EFFICIENT ALTERNATIVE METHODS OF PROVIDING THE BENEFITS INTENDED BY THE PROPOSAL. IF DEVELOPMENT OF SUCH ALTERNATIVES IS NOT PRACTICABLE, THE APPLICANT SHOULD JUSTIFY WHY NOT, INCLUDING REASONS AS TO WHY THEY WERE REJECTED.

As discussed in other responses and in information in the Attachments, proton therapy is the most clinically effective method for treating a significant number of cancers by means of radiation. It reduces patient side effects and decreases their risk of permanent injury and the development of secondary malignancies from the radiation treatments. As outlined by the studies referenced earlier in the application, the medical literature continues to demonstrate the benefits of proton therapy. The benefits are expected to increase as the proton therapy technology evolves and advances.

There is no proton therapy facility anywhere in the Middle Tennessee area and only two in operation in the Southeastern United States – Jacksonville, Florida and Knoxville, Tennessee. Neither facility is within a reasonable driving distance for patients who receive treatments daily, Monday through Friday. This project brings this beneficial new service into Middle Tennessee, where residents of parts of three other Southeastern states, Kentucky, Alabama, and Mississippi, will have good access to receive essential care or participate in ground-breaking research activities.

No better alternative provider for this service area has come forward, or been identified. The Provision team has successfully developed and financed the proton therapy center in Knoxville and, as a

result, has credibility in the markets to garner support for another center in Middle Tennessee. Funding a project of this magnitude through a tax-exempt bond issuance is a prudent and efficient approach that leverages available third-party capital rather than consuming the existing resources of hospital systems or other providers.

Other locations were considered, but the city of Franklin is the best location from which to serve the Primary and Secondary Service Area counties due to the availability of suitable, affordable land, close proximity to a tertiary hospital and other leading providers, ease of access for all of Middle Tennessee, and relatively minimal traffic congestion. The Williamson Medical Center/Carothers Parkway area is a burgeoning growth area for healthcare in the Middle Tennessee community. Williamson Medical Center (WMC) continues to grow and expand as evidenced by their latest collaboration with Vanderbilt University Medical Center to add a satellite Monroe Carrell Jr. Children's Hospital at WMC which is currently under construction. Adjacent to the WMC campus, HealthSouth is currently constructing a 40-bed Rehabilitation Hospital that is expected to be operational in the 4th quarter of 2015. Additionally, the newly built Carothers Parkway Medical Tower offers 4 floors of medical office space. Lastly, Vanderbilt University owns a 22-acre parcel along Carothers Parkway on which they intend to consolidate and develop medical services in the future.

B. THE APPLICANT SHOULD DOCUMENT THAT CONSIDERATION HAS BEEN GIVEN TO ALTERNATIVES TO NEW CONSTRUCTION, E.G., MODERNIZATION OR SHARING ARRANGEMENTS. IT SHOULD BE DOCUMENTED THAT SUPERIOR ALTERNATIVES HAVE BEEN IMPLEMENTED TO THE MAXIMUM EXTENT PRACTICABLE.

As discussed in the Project Description section, the unique requirements of this service (shielding, weight capacity) make it impossible to put in ordinary commercial buildings. New construction is required.

C(III).1. LIST ALL EXISTING HEALTH CARE PROVIDERS (I.E., HOSPITALS, NURSING HOMES, HOME CARE ORGANIZATIONS, ETC.) MANAGED CARE ORGANIZATIONS, ALLIANCES, AND/OR NETWORKS WITH WHICH THE APPLICANT CURRENTLY HAS OR PLANS TO HAVE CONTRACTUAL AGREEMENTS FOR HEALTH SERVICES.

The applicant anticipates having a contractual relationship with the Williamson Medical Center or other local providers for imaging support and other services. Emergency transfer agreements will also be proposed to Williamson Medical Center and to hospitals in Davidson County.

C(III).2. DESCRIBE THE POSITIVE AND/OR NEGATIVE EFFECTS OF THE PROPOSAL ON THE HEALTH CARE SYSTEM. PLEASE BE SURE TO DISCUSS ANY INSTANCES OF DUPLICATION OR COMPETITION ARISING FROM YOUR PROPOSAL, INCLUDING A DESCRIPTION OF THE EFFECT THE PROPOSAL WILL HAVE ON THE UTILIZATION RATES OF EXISTING PROVIDERS IN THE SERVICE AREA OF THE PROJECT.

The proton therapy project adds a valuable but currently unmet service to the wide array of cancer services currently existing in the Middle Tennessee area. Proton therapy is the most advanced method of delivering large curative radiation dosages into tumors while significantly reducing collateral damage and subsequent short and long-term side effects and the resultant expenses to treat them as shown by cost comparison studies referenced earlier in the application.

Proton Therapy does not duplicate linear accelerator technology, which uses photon beams to deliver radiation doses. Proton treatment rather is an option that complements existing radiation therapy services. The SHPC facility medical staff will be open, allowing any appropriately trained and credentialed radiation oncologists from the area healthcare systems to utilize its equipment for the benefit of their patients. The communities in this service area will be better served when this project becomes available.

SHPC will not have a significant adverse impact on linear accelerator utilization in the service area. SHPC's 569 patients from its primary service area represents only 6% of the 9,370 patients in those 38 counties who will need radiation therapy in CY2020. So its impact on existing and approved linear accelerator utilization will be minimal.

C(III).3. PROVIDE THE CURRENT AND/OR ANTICIPATED STAFFING PATTERN FOR ALL EMPLOYEES PROVIDING PATIENT CARE FOR THE PROJECT. THIS CAN BE REPORTED USING FTE'S FOR THESE POSITIONS. IN ADDITION, PLEASE COMPARE THE CLINICAL STAFF SALARIES IN THE PROPOSAL TO PREVAILING WAGE PATTERNS IN THE SERVICE AREA AS PUBLISHED BY THE TENNESSEE DEPARTMENT OF LABOR & WORKFORCE DEVELOPMENT AND/OR OTHER DOCUMENTED SOURCES.

Please see the following page for a chart of projected FTE's and salary ranges.

The Department of Labor, Bureau of Labor Statistics website indicates the following MSA (Nashville-Davidson-Murfreesboro-Franklin, TN) employment and annual wage information for clinical employees of this project:

May 2013 Occupational Employment and Wage Estimates					
Nashville-Davidson--Murfreesboro--Franklin, TN					
Occupation	Employment in specified area	Employment per 1000 jobs	Median hourly wage	Mean hourly wage	Annual mean wage
Registered Nurses	17,560	22.196	\$28.36	\$28.42	\$59,110
Radiation Therapists	70	0.091	\$33.03	\$33.99	\$70,700
Medical Assistants	4,560	5.759	\$14.70	\$15.21	\$31,640
Dietitians and Nutritionists	380	0.477	\$22.74	\$24.11	\$50,140
Compliance Officers	1,510	1.910	\$23.76	\$27.21	\$56,600
Counselors, All Other	140	0.175	\$18.68	\$18.70	\$38,900

Source: United States Department of Labor - Bureau of Labor Statistics

Scott Hamilton Proton Center 16 Hour Schedule Staffing Plan							
Positions	1st Shift	2nd Shift	Total	Pay Range		Total Range	
Radiation Therapist	9	6	15	\$55,000	\$75,000	\$825,000	\$1,125,000
Radiation Therapist /CT Sim	2	1	3	\$55,000	\$75,000	\$165,000	\$225,000
Registered Nurse	6	1	7	\$50,000	\$60,000	\$350,000	\$420,000
Medical Administrative Assistant	1	0	1	\$30,000	\$40,000	\$30,000	\$40,000
Medical Physicist, Chief	1	0	1	\$250,000	\$300,000	\$250,000	\$300,000
Medical Physicist, Staff	2	0.5	2.5	\$150,000	\$200,000	\$375,000	\$500,000
Medical Physicist, Board Eligible	1	0.5	1.5	\$120,000	\$130,000	\$180,000	\$195,000
Medical Dosimetrist	4	1.5	5.5	\$100,000	\$120,000	\$550,000	\$660,000
Dosimetry/Physics Assistant	1.5	1	2.5	\$60,000	\$70,000	\$150,000	\$175,000
Cancer Care Coordinator	2	1	3	\$30,000	\$50,000	\$90,000	\$150,000
Dietician	0.5	0	0.5	\$45,000	\$55,000	\$22,500	\$27,500
Compliance Coordinator	1	0	1	\$70,000	\$80,000	\$70,000	\$80,000
Research Coordinator	1	0	1	\$70,000	\$80,000	\$70,000	\$80,000
Social Worker	1	0.5	1.5	\$30,000	\$50,000	\$45,000	\$75,000
Financial Counselor	1.5	1	2.5	\$30,000	\$50,000	\$75,000	\$125,000
Subtotals	34.5	14	48.5				
TOTALS	48.5			\$1,145,000	\$1,435,000	\$3,247,500	\$4,177,500

C(III).4. DISCUSS THE AVAILABILITY OF AND ACCESSIBILITY TO HUMAN RESOURCES REQUIRED BY THE PROPOSAL, INCLUDING ADEQUATE PROFESSIONAL STAFF, AS PER THE DEPARTMENT OF HEALTH, THE DEPARTMENT OF MENTAL HEALTH AND DEVELOPMENTAL DISABILITIES, AND/OR THE DIVISION OF MENTAL RETARDATION SERVICES LICENSING REQUIREMENTS.

The applicant believes that the required personnel are readily available for recruitment. Recruitment will occur through word of mouth in the healthcare community, and through professional recruiters and print and internet advertising.

C(III).5. VERIFY THAT THE APPLICANT HAS REVIEWED AND UNDERSTANDS THE LICENSING CERTIFICATION AS REQUIRED BY THE STATE OF TENNESSEE FOR MEDICAL/CLINICAL STAFF. THESE INCLUDE, WITHOUT LIMITATION, REGULATIONS CONCERNING PHYSICIAN SUPERVISION, CREDENTIALING, ADMISSIONS PRIVILEGES, QUALITY ASSURANCE POLICIES AND PROGRAMS, UTILIZATION REVIEW PPOLICIES AND PROGRAMS, RECORD KEEPING, AND STAFF EDUCATION.

The applicant so verifies.

C(III).6. DISCUSS YOUR HEALTH CARE INSTITUTION'S PARTICIPATION IN THE TRAINING OF STUDENTS IN THE AREAS OF MEDICINE, NURSING, SOCIAL WORK, ETC. (I.E., INTERNSHIPS, RESIDENCIES, ETC.).

Training relationships have not yet been identified.

C(III).7(a). PLEASE VERIFY, AS APPLICABLE, THAT THE APPLICANT HAS REVIEWED AND UNDERSTANDS THE LICENSURE REQUIREMENTS OF THE DEPARTMENT OF HEALTH, THE DEPARTMENT OF MENTAL HEALTH AND DEVELOPMENTAL DISABILITIES, THE DIVISION OF MENTAL RETARDATION SERVICES, AND/OR ANY APPLICABLE MEDICARE REQUIREMENTS.

The applicant so verifies.

C(III).7(b). PROVIDE THE NAME OF THE ENTITY FROM WHICH THE APPLICANT HAS RECEIVED OR WILL RECEIVE LICENSURE, CERTIFICATION, AND/OR ACCREDITATION

The applicant will seek licensure, certified registration, certification, and accreditation from the following institutions.

LICENSURE: Tennessee Department of Environment & Conservation
Department of Radiological Health

**CERTIFIED
REGISTRATION:** Tennessee Department of Environment & Conservation
Department of Radiological Health

CERTIFICATION: Medicare Certification from CMS
TennCare Certification from TDH

ACCREDITATION: American College of Radiation Oncology

C(III).7(c). IF AN EXISTING INSTITUTION, PLEASE DESCRIBE THE CURRENT STANDING WITH ANY LICENSING, CERTIFYING, OR ACCREDITING AGENCY OR AGENCY.

Not applicable to a proposed new facility.

C(III).7(d). FOR EXISTING LICENSED PROVIDERS, DOCUMENT THAT ALL DEFICIENCIES (IF ANY) CITED IN THE LAST LICENSURE CERTIFICATION AND INSPECTION HAVE BEEN ADDRESSED THROUGH AN APPROVED PLAN OF CORRECTION. PLEASE INCLUDE A COPY OF THE MOST RECENT LICENSURE/CERTIFICATION INSPECTION WITH AN APPROVED PLAN OF CORRECTION.

Not applicable; Tennessee does not require licensure for this type of facility..

C(II)8. DOCUMENT AND EXPLAIN ANY FINAL ORDERS OR JUDGMENTS ENTERED IN ANY STATE OR COUNTRY BY A LICENSING AGENCY OR COURT AGAINST PROFESSIONAL LICENSES HELD BY THE APPLICANT OR ANY ENTITIES OR PERSONS WITH MORE THAN A 5% OWNERSHIP INTEREST IN THE APPLICANT. SUCH INFORMATION IS TO BE PROVIDED FOR LICENSES REGARDLESS OF WHETHER SUCH LICENSE IS CURRENTLY HELD.

None.

C(II)9. IDENTIFY AND EXPLAIN ANY FINAL CIVIL OR CRIMINAL JUDGMENTS FOR FRAUD OR THEFT AGAINST ANY PERSON OR ENTITY WITH MORE THAN A 5% OWNERSHIP INTEREST IN THE PROJECT.

None.

C(II)10. IF THE PROPOSAL IS APPROVED, PLEASE DISCUSS WHETHER THE APPLICANT WILL PROVIDE THE THSDA AND/OR THE REVIEWING AGENCY INFORMATION CONCERNING THE NUMBER OF PATIENTS TREATED, THE NUMBER AND TYPE OF PROCEDURES PERFORMED, AND OTHER DATA AS REQUIRED.

Yes. The applicant will provide the requested data consistent with Federal HIPAA requirements.

PROOF OF PUBLICATION

Attached.

DEVELOPMENT SCHEDULE

1. PLEASE COMPLETE THE PROJECT COMPLETION FORECAST CHART ON THE NEXT PAGE. IF THE PROJECT WILL BE COMPLETED IN MULTIPLE PHASES, PLEASE IDENTIFY THE ANTICIPATED COMPLETION DATE FOR EACH PHASE.

The Project Completion Forecast Chart is provided after this page.

PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision Date, as published in Rule 68-11-1609(c): 05/27/15

Assuming the CON decision becomes the final Agency action on that date, indicate the number of days from the above agency decision date to each phase of the completion forecast.

Dates Best Estimate Until Extension Filed		From 6/1/15
PHASE	DAYS REQUIRED	Anticipated Date (MONTH /YEAR)
1. Architectural & engineering contract signed	90	8/30/15
2. Construction documents approved by TDH	n/a	n/a
3. Construction contract signed	180	11/28/15
4. Building permit secured	210	12/28/15
5. Site preparation completed	355	5/21/16
6. Building construction commenced	415	7/20/16
7. Construction 40% complete	630	2/20/17
8. Construction 80% complete	845	9/23/17
9. Construction 100% complete	955	1/11/18
10. * Issuance of license	n/a	n/a
11. *Initiation of service	1311	1/2/19
12. Final architectural certification of payment	1401	4/2/19
13. Final Project Report Form (HF0055)	1492	7/2/19

*** For projects that do NOT involve construction or renovation: please complete items 10-11 only.**

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

2. IF THE RESPONSE TO THE PRECEDING QUESTION INDICATES THAT THE APPLICANT DOES NOT ANTICIPATE COMPLETING THE PROJECT WITHIN THE PERIOD OF VALIDITY AS DEFINED IN THE PRECEDING PARAGRAPH, PLEASE STATE BELOW ANY REQUEST FOR AN EXTENDED SCHEDULE AND DOCUMENT THE “GOOD CAUSE” FOR SUCH AN EXTENSION.

Due to the significant complexities of developing and constructing a proton therapy facility along with the applicant owner’s experience in such, SHPC requests a 4-year period of validity to implement the project. The Provision Center for Proton Therapy project was implemented over a 3 year 8 month period. A similar period will be needed for this project, to secure financing and perform site development, to construct the building with its large concrete-shielded multi-story vaults, to install the complex equipment and to complete equipment testing/acceptance and beam commissioning for treatment.

INDEX OF ATTACHMENTS

A.4	Ownership - Documentation of Legal Entities
A.5	Management Contract
A.6	Site Control
B.II.A.	Square Footage and Costs Per Square Footage Chart
B.II.E.1.	Fixed Major Medical Equipment-FDA Approval Documentation
B.II.E.3	Major Medical Equipment-Vendor Quotation
B.III.	Plot Plan
B.IV.	Floor Plan
C, Need-3	Service Area Maps
C, Economic Feasibility-1	Documentation of Construction Cost Estimate
C, Economic Feasibility-2	Documentation of Availability of Funding
C, Economic Feasibility-10	Financial Statements

A.4 - Ownership - Documentation of Legal Entities



STATE OF TENNESSEE
Tre Hargett, Secretary of State
Division of Business Services
William R. Snodgrass Tower
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

MTPC, LLC
STE 101
2095 LAKESIDE CENTRE WAY
KNOXVILLE, TN 37922-6647

December 18, 2014

Filing Acknowledgment

Please review the filing information below and notify our office immediately of any discrepancies.

SOS Control # :	781799	Formation Locale:	TENNESSEE
Filing Type:	Limited Liability Company - Domestic	Date Formed:	12/18/2014
Filing Date:	12/18/2014 1:49 PM	Fiscal Year Close:	12
Status:	Active	Annual Report Due:	04/01/2016
Duration Term:	Perpetual	Image # :	B0029-2528
Managed By:	Director Managed		
Business County:	KNOX COUNTY		

Document Receipt

Receipt # :	1742182	Filing Fee:	\$300.00
Payment-Check/MO - CFS-1, NASHVILLE, TN			\$300.00

Registered Agent Address:
MIKE SOMMI
STE 101
2095 LAKESIDE CENTRE WAY
KNOXVILLE, TN 37922-6647

Principal Address:
STE 101
2095 LAKESIDE CENTRE WAY
KNOXVILLE, TN 37922-6647

Congratulations on the successful filing of your **Articles of Organization** for **MTPC, LLC** in the State of Tennessee which is effective on the date shown above. You must also file this document in the office of the Register of Deeds in the county where the entity has its principal office if such principal office is in Tennessee. Please visit the Tennessee Department of Revenue website (apps.tn.gov/bizreg) to determine your online tax registration requirements. If you need to obtain a Certificate of Existence for this entity, you can request, pay for, and receive it from our website.

You must file an Annual Report with this office on or before the Annual Report Due Date noted above and maintain a Registered Office and Registered Agent. Failure to do so will subject the business to Administrative Dissolution/Revocation.

Tre Hargett
Secretary of State

Processed By: Nichole Hambrick

B0029-2528 12/18/2014 1:49 PM Received by Tennessee Secretary of State Tre Hargett

15

FILED

**ARTICLES OF ORGANIZATION
OF
MTPC, LLC**

The undersigned person, acting as Organizer of a limited liability company (the "Company") under the Tennessee Revised Limited Liability Company Act, Tennessee Code Annotated §48-249-101, et seq. (the "Act"), hereby adopts the following Articles of Organization for the Company:

1. Name. The name of the Company is MTPC, LLC and shall be referred to herein as the "Company".

2. Registered Agent and Office. The street address and zip code of the initial registered office of the Company, the county in which the office is located, and the name of the initial registered agent at that office are as follows:

- i. Name: Mike Sommi
- ii. Street Address: 2095 Lakeside Centre Way, Suite 101
Knoxville, Tennessee
- iii. Zip Code: 37922
- iv. County: Knox County

3. Principal Executive Office. The street address and zip code of the principal executive office of the Company and the county in which the office is located are as follows:

- i. Street Address: 2095 Lakeside Centre Way, Suite 101
Knoxville, Tennessee
- ii. Zip Code: 37922
- iii. County: Knox County

4. Organizer. The name and address of the Organizer of the Company are:

- i. Name: P. Newman Bankston
- ii. Street Address: 900 South Gay Street, Suite 1400
Knoxville, Tennessee
- iii. Zip Code: 37902

5. Director-Managed. The Company shall be director-managed. Any business of the Company shall be conducted under the exclusive management of its directors, except as otherwise provide by the Act or the Operating Agreement of the Company.

6. Charitable Purpose. The purposes for which the Company is organized are exclusively and solely for religious, charitable, scientific, literary and educational purposes within the meaning of Section 501(c)(3) of the Internal Revenue Code of 1986, as amended, or

the corresponding provision of any future federal tax code (herein, the "Code")

7. Member Limitation. The Company is irrevocably dedicated to and operated exclusively to further the charitable purposes of its members, all of which must be organizations qualifying for exemption under Section 501(c)(3) of the Code or governmental units or wholly owned instrumentalities of a state or political subdivision thereof (collectively, "Qualified Organizations").

8. Membership Transfer Restrictions. Any direct or indirect transfer of any membership interest in the Company to a transferee other than a Qualified Organization is prohibited.

9. Fair Market Value Exchange. The Company, interests in the Company (other than a membership interest), or its assets may only be availed of or transferred to (whether directly or indirectly) any nonmember other than a section 501(c)(3) organization or governmental unit or instrumentality in exchange for fair market value.

10. No Private Inurement or Benefit. No part of the net earnings of the Company shall inure to the benefit of, or be distributable to its directors, trustees, officers, or other private persons, except that the Company shall be authorized and empowered to pay reasonable compensation for services rendered to the Company and to make payments and distributions in furtherance of the purposes set forth herein.

11. No Substantial Lobbying. No substantial part of the activities of the Company shall be the carrying on of propaganda, or otherwise attempting to influence legislation.

12. No Political Campaigning. The Company shall not participate in, or intervene in (including the publishing or distribution of statements) any political campaign on behalf of or in opposition to any candidate for public office.

13. Amendment to the Articles of Organization. Any amendment to the Company's Articles of Organization and/or its Operating Agreement shall be consistent with Section 501(c)(3) of the Code.

14. Merger and Conversion. The Company is prohibited from merging with or converting into any entity that is not a Qualified Organization.

15. Other Restrictions. Notwithstanding any other provision of this Articles of Organization, the Company shall only carry on any activities permitted to be carried on (a) by a company exempt from federal income tax under Section 501(c)(3) of the Code, or (b) by a company, contributions to which are deductible under Section 170(c)(2) of the Code.

16. Power to Expel. The Company shall have the power and authority to expel one or more of its members if such member ceases to be a Qualified Organization, or as otherwise specified in the Company's Operating Agreement.

17. Distributions only to Qualified Organizations. The Company shall not distribute any of its assets to any member that ceases to be a Qualified Organization. Should any member of the Company cease to be a Qualified Organization, then such member shall be required to dispose of its membership interest in the Company in the manner provided in the Operating Agreement of the Company, but in no event shall such sale and purchase occur later than ninety (90) days following the date on which such member ceases to be a Qualified Organization.

18. Enforce Charitable Purposes. The Company's members shall expeditiously and vigorously enforce all of their rights in the Company and shall pursue all legal and equitable remedies to protect their interest in the Company.

19. Enforceability. All the provisions contained herein are consistent with Tennessee law, and are enforceable at law and in equity.

20. Period of Duration. The period of duration of the Company shall not be limited to a specific term of years.

21. Effective Date. The existence of the Company is to begin upon its filing of the Articles of Organization.

22. Indemnification. To the maximum extent permitted by the provisions of Tenn. Code Ann. § 48-249-115, as amended from time to time (provided, however, that if an amendment to such act limits or restricts in any way the indemnification rights permitted by law as of the date hereof, such amendment shall apply only to the extent mandated by law and only to activities of persons subject to indemnification under this paragraph which occur subsequent to the effective date of such amendment), the Company shall indemnify and advance expenses to any person, his or her heirs, executors and administrators, for the defense of any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative and whether formal or informal, including counsel fees actually incurred as a result of such action, suit or proceeding or any appeal thereof, and against all fines (including any excise tax assessed with respect to an employee benefit plan), judgments, penalties and amounts paid in settlement thereof, provided that such proceeding or action be instituted by reason of the fact that such person is or was a member of the Company. Any repeal or modification of the provisions of this Paragraph 20 directly or by the Company's adoption of an amendment to these Articles of Organization that is inconsistent with the provisions of this Paragraph 20, shall not adversely affect any right or protection set forth herein existing in favor of a particular individual at the time of such repeal or modification.

23. Dissolution. Upon the dissolution of the Company:

(a) all liabilities and obligations of the Company shall be paid and discharged, or adequate provisions shall be made therefor;

(b) assets held by the Company upon condition requiring return, transfer or conveyance, which condition occurs by reason of dissolution, shall be returned, transferred or conveyed in accordance with such requirements; and

(c) all remaining assets of the Company shall be distributed as follows:

(i) To its members, provided that any member receiving such distribution must be a Qualified Organization, or

(ii) To such organization or organizations organized and operated exclusively for religious, charitable, scientific, literary, or educational purposes as shall at the time qualify as an exempt organization or organizations under Section 501(c)(3) of the Code as the directors shall determine; or

(iii) To the State of Tennessee or to any county or municipality of such State, provided that such assets shall be used by the grantee exclusively for public purposes; or

(iv) As determined by a court of competent jurisdiction of the county in which the principal office of the Company is then located, exclusively for public purposes, or to such organization or organizations, as said court shall determine, which are organized and operated exclusively for such purposes.

Executed as of this 18th day of December, 2014.



P. Newman Bankston, Organizer

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As of February 04, 2015 we have processed all corporate filings received in our office through February 03, 2015 and all annual reports received in our office through February 03, 2015.

Click on the underlined control number of the entity in the search results list to proceed to the detail page. From the detail page you can verify the entity displayed is correct (review addresses and business details) and select from the available entity actions - file an annual report, obtain a certificate of existence, file an amendment, etc.

Search:
1-1 of 1

Search Name:

Control #:

Active Entities Only: ☐

Control #	Entity Type	Name	Name Type	Name Status	Entity Filing Date	Entity Status
<u>000781799</u>	LLC	MTPC, LLC TENNESSEE	Entity	Active	12/18/2014	Active

1-1 of 1

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STATE OF TENNESSEE
Tre Hargett, Secretary of State
Division of Business Services
William R. Snodgrass Tower
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

Provision Proton Centers, LLC
STE 101
2095 LAKESIDE CENTRE WAY
KNOXVILLE, TN 37922-6647

January 10, 2014

Filing Acknowledgment

Please review the filing information below and notify our office immediately of any discrepancies.

Control # : 743298 Status: Active
Filing Type: Limited Liability Company - Domestic

Document Receipt

Receipt # : 1262937 Filing Fee: \$20.00
Payment-Check/MO - CFS-1, NASHVILLE, TN \$20.00

Amendment Type: Amended and Restated Formation Documents Image # : 7271-0879
Filed Date: 01/10/2014 3:07 PM

This will acknowledge the filing of the attached amended and restated formation document with an effective date as indicated above. When corresponding with this office or submitting documents for filing, please refer to the control number given above.

You must also file this document in the office of the Register of Deeds in the county where the entity has its principal office if such principal office is in Tennessee.

Tre Hargett
Secretary of State

Processed By: Kathy Sherrell

Field Name	Changed From	Changed To
Registered Agent #	0519628	0410149
Registered Agent First Name	TERRY	ANNE
Registered Agent Last Name	DOUGLAS	SALE
Registered Agent Middle Name	D.	H
Registered Agent Physical Address 1	1400 DOWELL SPRINGS BLVD	2095 LAKESIDE CENTRE WAY
Registered Agent Physical Address 2	No Value	STE 101
Registered Agent Physical Postal Code	37909-2456	37922-6647

FIRST AMENDED AND RESTATED ARTICLES OF ORGANIZATION

OF

FILED

PROVISION PROTON CENTERS, LLC

The undersigned limited liability company (the "Company"), organized under the Tennessee Revised Limited Liability Company Act, Tennessee Code Annotated Sections 48-249-101 *et seq.* (the "Act"), hereby adopts the following First Amended and Restated Articles of Organization pursuant to Section 48-249-204 of the Act.

The initial Articles of Organization were filed with the Secretary of State of Tennessee on January 10, 2014. The Control Number of the Company is 743298.

1. **Name.** The name of the Company is:

Provision Proton Centers, LLC

2. **Registered Agent and Office.**

The name of the initial registered agent of the Company and the street address, zip code and county of the initial registered office of the Company are:

Anne Sale
2095 Lakeside Centre Way, Suite 101
Knoxville, Tennessee 37922-6647
Knox County, Tennessee

3. **Principal Executive Office.**

The street address, zip code and county of the principal executive office of the Company are:

2095 Lakeside Centre Way, Suite 101
Knoxville, Tennessee 37922-6647
Knox County, Tennessee

4. **Management.** The Company shall be director-managed.

5. **Operating Agreement.** Any operating agreement entered into by members of the Company and any amendments thereto must be in writing.

This 10th day of January, 2014.

PROVISION PROTON CENTERS, LLC

By: Dennis R. McClane
Dennis R. McClane
Organizer

7271.0075. 11/10/2014, 15:07:24, Received by Tennessee Secretary of State Tre Harwell

**CERTIFICATE REGARDING FIRST AMENDED AND RESTATED
ARTICLES OF ORGANIZATION OF
PROVISION PROTON CENTERS, LLC**

The undersigned Organizer of Provision Proton Centers, LLC (the "Company") hereby certifies to the Secretary of State of Tennessee as follows:

1. The name of the Company is Provision Proton Centers, LLC. The Control Number of the Company is 743298.

2. The foregoing First Amended and Restated Articles of Organization amend the initial Articles of Organization by amending Paragraph 2 of the initial Articles of Organization to change the name of the registered agent and the street address of the registered office as set forth in the foregoing First Amended and Restated Articles of Organization. These amendments were adopted on January 10, 2014.

3. The foregoing First Amended and Restated Articles of Organization were approved by the Company on January 10, 2014.

This Certificate is made and filed pursuant to Section 48-249-204 of the Tennessee Revised Limited Liability Company Act.

This 10th day of January, 2014.

PROVISION PROTON CENTERS, LLC

By:

Dennis R. McClane

Dennis R. McClane
Organizer

Page: 2 OF 2
201401130042030

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Tennessee Secretary of State

Tre Hargett

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Search: 1-1 of 1

Search Name: ☐ Starts With ☐ Contains

Control #:

Active Entities Only: ☐

Control #	Entity Type	Name	Name Type	Name Status	Entity Filing Date	Entity Status
<u>000743298</u>	LLC	Provision Proton Centers, LLC TENNESSEE	Entity	Active	01/10/2014	Active

1-1 of 1

Information about individual business entities can be queried, viewed and printed using this search tool for free.

If you want to get an electronic file of all business entities in the database, the full database can be downloaded for a fee by [Clicking Here](#).

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A.5 - Management Contract

MANAGEMENT SERVICES AGREEMENT

This Management Services Agreement (the "Agreement") is made and entered into effective as of _____ (the "Effective Date") by and between MTPC, LLC d/b/a The Scott Hamilton Proton Center, a Tennessee limited liability company ("MTPC"), and Provision Proton Centers, LLC, a Tennessee limited liability company ("PROVISION").

RECITALS

WHEREAS, MTPC operates a proton therapy center located at Carothers Parkway in Franklin, Tennessee (the "Center"); and

WHEREAS, PROVISION is a billing and healthcare management services company with expertise in providing operational and financial management services ("Management Services") to proton therapy centers; and

WHEREAS, MTPC desires to engage PROVISION to provide Management Services in connection with the operation of the Center, according to the terms of this Agreement;

NOW, THEREFORE, in consideration of the mutual promises, covenants and agreements contained herein, and other good and valuable consideration, the receipt and sufficiency of which is acknowledged, MTPC and PROVISION hereby agree as follows:

ARTICLE I ENGAGEMENT OF PROVISION

Section 1.1. Appointment of PROVISION as Manager. MTPC hereby appoints PROVISION as the sole and exclusive manager of the Center to perform the Management Services as more specifically described in Article II during the Term (as defined below) upon the terms and conditions stated in this Agreement, and PROVISION hereby accepts such appointment. PROVISION's appointment and duties, as set forth in this Agreement, shall at all times be subject to oversight and control by the MTPC Board of Directors (the "Board"), including, without limitation, any policies and procedures adopted by the Board as well as the terms of MTPC's Operating Agreement.

ARTICLE II DUTIES OF PROVISION

Section 2.1. Management Services. Subject to the rights and duties of the Board, during the Term, PROVISION shall provide such management services as are reasonably necessary and appropriate for the day-to-day operation of the Center. Without limiting the generality of the foregoing, PROVISION's duties shall include the following with respect to the Center:

(a) providing general administrative supervision and oversight of the Center's operations, and establishing, implementing, and maintaining administrative office policies and procedures for the Center;

(b) supervising all technical and other non-physician personnel required in connection with the operation of the Center ("Center Personnel"), and maintaining responsibility for personnel administration, human resources, training, and assignment of duties for all such Center Personnel. PROVISION shall train Center Personnel with respect to all aspects of the Center's operations (other than clinical, medical or patient care), including but not limited to, administrative, financial and information technology matters;

(c) establishing and administering accounting procedures, controls and systems for the development, preparation and keeping of records and books of accounting related to the business and financial affairs of the Center. Such accounting procedures, controls and systems shall include, but are not limited to, accounts payable, bank reconciliations, cash flow projections and cash flow management, financial statement preparation, maintaining the Center's general ledger, and providing payroll services for the Center;

(d) preparing annual operating and capital budgets, and monthly financial reports for the Center as required by the Board, bond holders or other creditors;

(e) periodically reviewing business operations and financial matters of the Center;

(f) establishing the Center's bank accounts and managing such accounts and the Center's banking services;

(g) procuring insurance on behalf of MTPC in accordance with Section 7.1 if not previously procured by MTPC;

(h) negotiating, either directly or on MTPC's behalf, as appropriate and permitted by applicable law, such contractual arrangements with third parties as are reasonably necessary and appropriate for MTPC's provision of healthcare services at the Center provided that all contracts or arrangements regarding the provision of care or services at the Center will be executed by MTPC or shall be entered into with MTPC's consent;

(i) assisting the Center in maintaining compliance with all legal requirements pertaining to the operation of the Center, including, without limitation, compliance with HIPAA and radiation safety legal requirements, and establishing and administering the Center's corporate compliance program;

(j) assisting the Center in obtaining and maintaining necessary state licenses, Medicare and Medicaid certifications and accreditations;

(k) exercising reasonable efforts to bill and collect, or arrange for a third party billing and collection services company to bill and collect, in a timely manner, all professional and other fees for all billable services provided by the Center. In connection with the billing and collection services to be provided hereunder, MTPC hereby appoints PROVISION (or its designee) as

MTPC's true and lawful agent, and PROVISION hereby accepts such appointment, solely for the following purposes:

(i) To bill (or arrange for the billing), in MTPC's name and on MTPC's behalf, all claims for reimbursement from patients, insurance companies and plans, all state or federally funded benefit plans, and all other third party payors or Medicare Administrative Contractors and for all covered billable medical care provided by or on behalf of the Center; and

(ii) To collect and receive (or arrange for the collection and receipt), in MTPC's name and on MTPC's behalf, all accounts receivable generated by the Center's billings and claims for reimbursement, to take possession of, endorse in the name of MTPC, and deposit into MTPC's account any notes, checks, money orders, insurance payments, and any other instruments received in payment of accounts receivable for medical care provided at the Center, to administer such accounts including, but not limited to, extending the time or payment of any such accounts for cash, credit or otherwise; discharging or releasing the obligors of any such accounts; suing, assigning or selling at a discount such accounts to collection agencies; or taking other measures to require the payment of any such accounts; provided, however, that extraordinary collection measures, such as filing lawsuits, discharging or releasing obligors, or assigning or selling accounts at a discount to collection agencies shall not be undertaken without MTPC's consent;

(l) depositing in MTPC's account all governmental payor (i.e., Medicare, Medicaid, TennCare, TRICARE, etc.) collections collected by MTPC or by PROVISION on MTPC's behalf pursuant to Section 2.1(f) above (or any other payments required by law to pass first through the sole control of MTPC) with respect to services provided at the Center. To the extent that MTPC, any of its employees or agents receives funds for services paid for or reimbursed by governmental payors, such funds shall be deposited in MTPC's account;

(m) coordinating strategic planning and developing relationships for the Center;

(n) developing, establishing and implementing a culture of care and service with supportive policies that will differentiate the Center from other proton therapy centers and local healthcare providers;

(o) developing, implementing, overseeing and managing a medical tourism initiative; and

(p) other such development, management and oversight services necessary for the successful operation of the Center.

Section 2.2. Additional Services for MTPC. In addition to the Management Services, PROVISION may also provide marketing and public relations services to MTPC from time to time as requested by MTPC. This may include assisting MTPC in developing, marketing and advertising programs to effectively notify the community of the services offered by the Center. Marketing services shall include, but shall not be limited to, marketing to both physicians and patients, producing marketing materials, web site content, direct mail, and social media exposure. The parties expressly acknowledge and agree that MTPC shall exercise control over all policies and decisions relating to every element of such advertising. PROVISION and MTPC agree that all

such marketing and advertising programs shall be conducted in compliance with all applicable standards of medical ethics, laws and regulations.

Section 2.3. PROVISION as Agent for MTPC. The parties intend by this Agreement solely to effect the appointment of PROVISION for operational and administrative management of the Center as described herein, and this Agreement does not extend to or involve any other activities of either party. In carrying out its obligations hereunder, PROVISION is acting solely as agent for and on behalf of and for the account of MTPC, and nothing in this Agreement shall create or be construed to create a partnership or joint venture relationship between MTPC and PROVISION, but rather only the relationship of principal and agent for those specific duties assigned to PROVISION in this Agreement.

Section 2.4. Center Obligations. All debts and liabilities to third persons incurred by PROVISION in connection with the operation of the Center will be debts and liabilities of MTPC only (such obligations, the "Center Obligations"). PROVISION will not be liable for any such Center Obligations by reason of its management, supervision, direction and/or operation of the Center for MTPC, subject to PROVISION's indemnification obligations in Article VI.

Section 2.5. Patient Records. At all times during the Term, access to patient records in connection with the operation of the Center will be governed by applicable state and federal laws governing confidentiality of patient records. Upon termination of this Agreement, MTPC will retain all patient medical records maintained in connection with the operation of the Center. PROVISION shall have no ownership rights or other right to possession of the patient records utilized in the operation of the Center. In the event of litigation or other situations when access to medical records by PROVISION is required, whether during or after the Term of this Agreement, PROVISION will be provided reasonable access to such records with permission to reproduce appropriate portions thereof at PROVISION's expense in conformance with applicable Tennessee and Federal confidentiality and privacy requirements.

Section 2.6. Approval of Operating and Capital Budgets. The annual operating and capital budgets for the Center required by Section 2.1 will be submitted by PROVISION to MTPC for approval at least sixty (60) days before the beginning of each fiscal year. MTPC and PROVISION shall cooperate and use their reasonable best efforts to cause such operating and capital budgets to be approved by MTPC at least thirty (30) days before the beginning of each fiscal year. PROVISION shall use reasonable best efforts to cause the Center to be managed within such budgets, and any deviations from the capital budget, or operating expenses of the operating budget, in excess of \$25,000 in any fiscal year will require the prior approval of MTPC (which approval will not be unreasonably withheld).

ARTICLE III OBLIGATIONS OF MTPC

Section 3.1. Freedom to Make Medical Decisions. Notwithstanding any provision to the contrary, physicians and other licensed medical practitioners shall be free to make clinical decisions ("Clinical Decisions") in the best interests of their patients without influence by PROVISION's direction, coordination and management of the Center programs and

operations, or the supervision of persons providing technical services that support the medical services such physicians and other medical licensees provide to their patients. PROVISION shall not be responsible for any liability or loss of any kind associated with a clinical decision made by a physician or other licensed medical practitioner whose patients utilize the Center.

Section 3.2. Medical Director. MTPC shall appoint a physician who is qualified by education, training, and experience to serve as Medical Director of the Center and who shall direct the medical activities of the Center. The Medical Director shall provide general supervision of the medical services provided at the Center to ensure that medical standards of CMS and other reimbursement and licensing authorities are met and assist in the development and implementation of policies regarding patient care.

Section 3.4. Cooperation with PROVISION. MTPC and PROVISION shall reasonably cooperate with each other in the performance of all duties under this Agreement.

ARTICLE IV TERM AND TERMINATION

Section 4.1. Term. The Initial Term of this Agreement shall commence on the Effective Date, and shall expire on the first (1st) anniversary thereof unless sooner terminated pursuant to the terms of this Agreement (the "Initial Term," together with any Renewal Terms (as defined below), the "Term").

Section 4.2. Renewal Term. After the Initial Term, this Agreement shall automatically renew for a successive one (1) year term (the "Renewal Term"), unless written notice of either party's intention not to renew is delivered to the other party at least ninety (90) days prior to the Renewal Term.

Section 4.3. Termination Without Cause. This Agreement may be terminated without cause at any time upon the mutual written consent of both parties. Additionally, at any time after the Initial Term, either party may terminate this Agreement without cause upon 180 days advance written notice.

Section 4.4. Material Breach. Either party shall be in default of this Agreement if such party fails to perform any material term hereof, and such failure is not cured within thirty (30) days after receipt of written notification of such failure from the party not in default. Notwithstanding the foregoing, in the event the party receiving notice of such material breach disputes the existence of such breach, the provisions of Sections 9.17 and 9.18 will apply. In the event of such default, the non-defaulting party shall have the right to terminate this Agreement immediately by written notice to the other party.

Section 4.5. Bankruptcy. In the event either party files a petition in bankruptcy, makes an assignment for the benefit of creditors, is adjudicated insolvent or bankrupt, petitions or applies for a receiver or trustee for a substantial part of its property, commences any proceeding under any reorganization arrangement, dissolution or liquidation law or statute of any jurisdiction, or if there is commenced against the other party any such proceeding which has not been dismissed sixty (60) days after its commencement, the other party may terminate this Agreement by providing written notice to such party.

Section 4.6. Other Provisions. This Agreement may be terminated by PROVISION or MTPC pursuant to the provisions of Section 9.1.

Section 4.7. Effect of Termination. Upon termination of this Agreement, all amounts due and owing between the parties through the date of termination will become immediately due and payable. Notwithstanding any provisions of this Agreement to the contrary, where express provision is made for the survival of certain rights or obligations of the parties, such rights and obligations will survive the expiration or earlier termination of this Agreement. The parties agree that the expiration or earlier termination of this Agreement shall not affect the rights of either party to damages based on any breach by the other party, or indemnification pursuant to the provisions of Article VI.

Section 4.8. Collections at Termination. Upon the expiration or earlier termination of this Agreement for any reason, MTPC specifically acknowledges and agrees that PROVISION will be entitled to continue to administer the collection of and receipt on behalf of MTPC of all cash collections from accounts receivable for services rendered prior to the date of termination, it being understood that such cash collections will be applied in accordance with Article V until PROVISION is compensated for all fees payable to PROVISION hereunder.

Section 4.9. Set-Off Rights. In the event of any default hereunder by MTPC, PROVISION may, upon written notice to MTPC, set-off any cash collections received in connection with the operation of the Center and apply such amounts in accordance with Article V until PROVISION is compensated for all fees payable to PROVISION hereunder.

ARTICLE V PAYMENTS TO PROVISION

Section 5.1. Management Fees. As consideration for the provision of Management Services rendered under this Agreement, as described in Section 2.1 above, MTPC shall pay to PROVISION an annual fee of one million eight hundred and fifty one thousand, nine hundred and ninety one dollars (\$1,851,991) in equal monthly installments during the first year of operation and two million eight hundred and eighty two thousand nine hundred and forty four dollars (\$2,882,944) in equal monthly installments during the second year of operation (the "Management Fee"), representing the fair market value of such Management Services and reasonably related to the value of such Management Services, as supported by an appraisal of an independent third party with expertise in reviewing and determining fair market value in arrangements similar to that contemplated herein. Such payments shall be made monthly, in arrears, and shall be due thirty (30) days following the receipt and acceptance by MTPC of PROVISION's monthly invoice.

Section 5.2. Expenses. MTPC will reimburse PROVISION for all approved expenses and obligations incurred by PROVISION in connection with the performance of its services and obligations hereunder, payable in accordance with Section 5.3 below, including but not limited to the following:

(a) All Center Obligations incurred by PROVISION on behalf of MTPC pursuant to Section 2.4.

(b) All marketing expenses (within the annual budgets approved in accordance with Section 2.5) incurred by PROVISION (the "Marketing Expenses") in connection with the performance of its obligations hereunder.

Section 5.3. Payment of Fees and Expenses.

(a) MTPC will pay PROVISION the foregoing fees payable during any calendar month, and will reimburse PROVISION for the Center Obligations and expenses incurred by PROVISION during any calendar month, within thirty (30) business days of receiving a properly documented invoice. In the event the fees or such expenses payable hereunder are not paid by MTPC when due as set forth above, interest will accrue on such unpaid amount at the lesser of (i) twelve percent (12%) per annum, or (ii) the maximum rate permitted by applicable law. PROVISION has the right to review and audit the books and records of the Center from at any time during the Term to confirm all amounts payable hereunder by MTPC to PROVISION during the Term.

(b) Within sixty (60) days from the end of each fiscal year, the exact amount of the fees due PIHP from MTPC for such fiscal year, or portion thereof, will be computed. If the fees paid to PROVISION by MTPC during such fiscal year were less than the calculated fees due for the fiscal year, then MTPC shall pay to PROVISION such difference within twenty (20) business days of the determination thereof. If the fees paid to PROVISION by MTPC during such fiscal year were more than the calculated fees due for the fiscal year, then PROVISION shall pay to MTPC such difference within twenty (20) business days of the determination thereof. If at any time any payment made by MTPC hereunder is inconsistent with the terms of this Agreement, MTPC may adjust future payments from time to time, or require repayment from PROVISION during the term of this Agreement, in order to ensure that total payments made over the term of this Agreement are consistent with the terms of this Agreement.

Section 5.4. Reasonable Value. MTPC's payment to PROVISION of the fees and the expenses payable hereunder is not intended and will not be interpreted or implied as permitting PROVISION to share in MTPC's fees for medical services, and the payment of such amounts is acknowledged to be the parties' negotiated agreement regarding the reasonable fair market value of the services provided by, and the other obligations of, PROVISION pursuant to this Agreement.

Section 5.5. Annual Review. Within sixty (60) days of each anniversary of the Effective Date, the parties will review the fees payable under Article V, to confirm such fees are consistent with fair market value and reasonably related to the value of the services provided hereunder. PROVISION will notify MTPC of any changes in such fees within thirty (30) days of each anniversary of the Effective Date, and the parties will execute an amendment to this Agreement reflecting such changes; provided, that if such changes are not acceptable to MTPC, then either party may terminate this Agreement in accordance with Section 4.3 hereof.

ARTICLE VI INDEMNIFICATION

Section 6.1. Indemnification by MTPC. MTPC shall indemnify and hold harmless PROVISION and its directors, officers, employees, agents, affiliates, subsidiaries and representatives from and against any and all claims, demands, damages, liabilities, costs, or expenses (including reasonable attorneys' fees and expenses), whether or not in connection with a third-party claim, arising out of or in connection with (i) any injury, death or property or other damage to any third party in connection with the Center (including patients referred to the Center, employees, licensees and invitees of MTPC or the Center) and the use of the PROVISION RIS/PACS System, and any breach by MTPC of its obligations under this agreement; provided, however, that the indemnification provided pursuant to the terms of this Section 6.1 will not apply to the extent arising out of the actions or inactions of PROVISION or its employees or agents. The provisions of this Section 6.1 will survive the expiration or termination of this Agreement for any reason.

Section 6.2. Indemnification by PROVISION. PROVISION shall indemnify and hold harmless MTPC and its directors, officers, employees, agents, affiliates, subsidiaries and representatives from and against any and all claims, demands, damages, liabilities, costs, or expenses (including reasonable attorneys' fees and expenses), whether or not in connection with a third-party claim, arising out of or in connection with (i) any actions or inactions of PROVISION or its employees or agents, and (ii) any breach by PROVISION of its obligations under this agreement; provided, however, that the indemnification provided pursuant to the terms of this Section 6.2 will not apply to the extent arising out of the actions or inactions of MTPC or its employees or agents. The provisions of this Section 6.2 will survive the expiration or termination of this Agreement for any reason.

ARTICLE VII INSURANCE; DAMAGE TO OR SUSPENSION OF CENTER OPERATIONS

Section 7.1. Insurance to be Maintained by MTPC. MTPC shall, at its sole expense, procure and maintain in full force and effect at all times during the Term, comprehensive general liability, property and professional liability insurance for the Center and the operations consistent with community standards for facilities similar to the Center; provided, however, that if MTPC directs PROVISION to obtain such insurance or if MTPC is unable to obtain any such insurance during the Term, PROVISION shall, at the expense of MTPC, obtain such insurance on behalf of and in the name of MTPC. All insurance required hereunder shall be written with a reputable insurance company or companies authorized to conduct business in Tennessee. Each insurance policy maintained by MTPC (whether or not obtained by PROVISION or by MTPC) shall name PROVISION as an additional insured, and shall require the insurance company to notify PROVISION at least thirty (30) days in advance of cancellation or lapse. Upon termination of this Agreement for any reason, MTPC shall obtain comprehensive general liability and professional liability tail coverage covering PROVISION with respect to the period this Agreement was in effect. MTPC hereby waives any right of contribution with respect to a loss covered under such policies (or their deductibles) against PROVISION or the insurance carrier. MTPC assumes all risks in connection with the adequacy of any insurance obtained hereunder, and waives, indemnifies and holds harmless PROVISION from and against any claim against PROVISION or their respective directors,

officers, subsidiaries, affiliates, employees, agents or representatives for any liability, cost or expense arising out of any uninsured claim, in part or in full, of any nature whatsoever, to the extent PROVISION is entitled to indemnification hereunder.

Section 7.2. Insurance to be Maintained by PROVISION. PROVISION shall, at its sole expense, procure and maintain in full force and effect at all times during the Term, comprehensive general liability, property and professional liability insurance in connection with the services provided by PROVISION hereunder. All insurance required hereunder shall be written with a reputable insurance company or companies authorized to conduct business in Tennessee. Each insurance policy maintained by PROVISION shall name MTPC as an additional insured, and shall require the insurance company to notify MTPC at least thirty (30) days in advance of cancellation or lapse. Upon termination of this Agreement for any reason, PROVISION shall obtain comprehensive general liability and professional liability tail coverage covering MTPC with respect to the period this Agreement was in effect. PROVISION hereby waives any right of contribution with respect to a loss covered under such policies (or their deductibles) against MTPC or the insurance carrier.

ARTICLE VIII CONFIDENTIALITY/RECORDS OWNERSHIP

Section 8.1. Confidentiality/Record Ownership. Each party will hold in strict confidence any confidential or proprietary information it receives from the other party in connection with this Agreement (any such information, the "Confidential Information"). The obligations of the parties hereunder will not apply to the extent that the disclosure of information otherwise determined to be confidential is required by applicable law; provided, however, that prior to disclosing such confidential information, the disclosing party must notify the other party thereof, which notice will include the basis upon which the disclosing party believes the information is required to be disclosed. In order to protect the Confidential Information, MTPC and PROVISION covenant that: (i) at any time, either during or subsequent to the Term, such party will not, without the other party's prior written consent, disclose to others, use, copy or permit to be copied the Confidential Information of the other party, except pursuant to their duties and obligations under this Agreement or except as otherwise required by law, and (ii) promptly upon the expiration or earlier termination of this Agreement for any reason, each party will, if requested by the other party, return to the other party all originals and copies of all reports, records, memoranda and other materials that contain the Confidential Information of the other party, including originals and copies of all such reports, records, memoranda and other materials prepared by the other party. The provisions of this Section 8.1 will survive the expiration or termination of this Agreement.

Section 8.2. Remedies. The parties acknowledge and agree that either party would be damaged irreparably in the event of a breach of Section 8.1 by the other party and that any such breach could not be adequately compensated by monetary damages. Accordingly, each party agrees that, in addition to any other right or remedy to which the parties may be entitled, at law or in equity, the parties will be entitled to enforce Section 8.1 of this Agreement by temporary, preliminary and permanent injunctive relief to prevent breaches or threatened breaches of Section 8.1 of this Agreement, without posting any bond or other undertaking.

ARTICLE IX MISCELLANEOUS

Section 9.1. Regulatory Event. This Agreement will be construed to be in accordance with all federal and state laws, including laws relating to Medicare, Medicaid and other third party payors. In the event there is a change in such laws, whether by statute, regulation, agency or judicial decision, that has any material effect on any term of this Agreement, then the applicable term(s) of the Agreement will be subject to renegotiation, and either party may request renegotiation of the affected term or terms of this Agreement, upon written notice to the other party, to remedy such condition. The parties expressly recognize that upon request for renegotiation, each party has a duty and obligation to the other party only to renegotiate the affected term(s) in good faith and, further, each party expressly agrees that its consent to proposals submitted by the other party during renegotiation efforts will not be unreasonably withheld. If the parties are unable to renegotiate the term or terms so affected so as to bring it/them into compliance with the statute, regulation, or judicial or agency opinion or interpretation that rendered it/them unlawful or unenforceable within thirty (30) days of the date on which notice of a desired renegotiation is given, then either party shall be entitled, after the expiration of such thirty (30) day period, to terminate this Agreement upon thirty (30) additional days' written notice to the other party.

Section 9.2. Access to Books and Records of Center by Governmental Authorities. Upon written request of the Secretary of the Department of Health and Human Services or the Comptroller General or any other duly authorized representatives thereof, either party hereto or any other related organization providing services with a value or cost of Ten Thousand Dollars (\$10,000) or more over a twelve (12) month period, shall make available to the Secretary those contracts, books, documents and records necessary to verify the nature and extent of the cost of providing its services. Such inspection shall be available up to four (4) years after such services are rendered.

Section 9.3. Assignment; Successors and Assigns. MTPC shall not assign its rights or obligations under this Agreement without the prior written consent of PROVISION. PROVISION may assign its rights and obligations under this Agreement to a related or successor entity.

Section 9.4. Other Business Activities. MTPC acknowledges that PROVISION and its affiliates may engage in the business of providing management services to other entities or practices in addition to the services that will be provided to MTPC hereunder. Nothing in this Agreement will prohibit PROVISION or any of its affiliates from entering into such arrangements.

Section 9.5. Notices. All notices, consents, waivers, and other communications under this Agreement must be in writing and will be deemed to have been duly given when (a) delivered by hand (with written confirmation of receipt), (b) sent by facsimile with confirmation of transmission by the transmitting equipment, (c) received by the addressee, if sent by certified mail, return receipt requested, or (d) received by the addressee, if sent by a nationally recognized overnight delivery service, return receipt requested, in each case to the

appropriate addresses or facsimile numbers set forth below (or to such other addresses or facsimile numbers as a party may designate by notice to the other party):

PROVISION:

Provision Proton Centers, LLC
Attn:

MTPC:

MTPC, LLC
Carrothers Parkway
Franklin, Tennessee
Attn:

Section 9.6. Entire Agreement, Modifications. This Agreement constitutes the entire agreement of the parties with respect to the subject matter hereof and supersedes all prior contracts or agreements with respect thereto, whether oral or written. It is understood that the terms of this agreement may be further negotiated should either party determine that the consideration exchanged herein does not represent a fair market value exchange. Should either party seek to initiate such a renegotiation the parties agree that they will negotiate in good faith and in the absence of agreement, submit their differences to a mutually agreeable independent third-party mediator within 30 days of the date that the first patient is treated in the center. The decision in such mediation will be binding. Further, this Agreement may be modified only in writing signed by the parties hereto.

Section 9.7. Governing Law. This Agreement will be governed by and interpreted according to the substantive laws of the State of Tennessee, without regard to its conflict of law rules.

Section 9.8. Expenses. Each party to this Agreement will bear its respective expenses incurred in connection with the preparation, execution and performance of this Agreement.

Section 9.9. Force Majeure. A party will be excused for failures and delays in performance of its obligations under this Agreement due to any cause beyond the control and without the fault of such party, including, without limitation, any act of God, war, riot or insurrection, law or regulation, strike, flood, fire, explosion or inability due to any of the aforementioned causes to obtain necessary labor or materials. This provision will not, however, release such party from using its reasonable best efforts to avoid or remove such cause and such party shall continue performance under this Agreement with the utmost dispatch whenever such cause is removed. Upon claiming any such excuse or delay for nonperformance, such party shall give prompt written notice thereof to the other party, provided that failure to give such notice will not in any way affect the benefit of this provision.

Section 9.10. Construction. Whenever the context requires, the gender of all words used in this Agreement includes the masculine, feminine, and neuter. All references to Articles and Sections refer to articles and sections of this Agreement, and all references to

Exhibits are to exhibits attached hereto, each of which is made a part hereof for all purposes. **The language used in this Agreement will be construed, in all cases, according to its fair meaning, and not for or against any party hereto. The parties acknowledge that each party has reviewed this Agreement and that rules of construction to the effect that any ambiguities are to be resolved against the drafting party will not be available in the interpretation of this Agreement.**

Section 9.11. Further Assurances. Each party agrees to do all acts and things and to make, execute and deliver such written instruments, as may from time to time be reasonably required to carry out the provisions of this Agreement.

Section 9.12. No Waiver. No failure to exercise, and no delay in exercising, on the part of either party, any privilege, any power or any right hereunder will operate as a waiver thereof, nor will any single or partial exercise of any privilege, right or power hereunder preclude further exercise of any other privilege, right or power hereunder.

Section 9.13. Severability. If any provision of this Agreement is held invalid or unenforceable by any court of competent jurisdiction, the other provisions of this Agreement will remain in full force and effect. The parties further agree that if any provision contained herein is, to any extent, held invalid or unenforceable in any respect under the laws governing this Agreement, they will take any actions necessary to render the remaining provisions of this Agreement valid and enforceable to the fullest extent permitted by law and, to the extent necessary, will amend or otherwise modify this Agreement to replace any provision contained herein that is held invalid or unenforceable with a valid and enforceable provision giving effect to the intent of the parties.

Section 9.14. Third Party Beneficiaries. The agreements and covenants contained in this Agreement inure solely to the benefit of the parties hereto. Except in an action brought by, but not on behalf of, a party, no provision of this Agreement is specifically enforceable, and no provision of this Agreement will be construed to create any third-party beneficiary claims.

Section 9.15. Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Agreement and all of which, when taken together, will be deemed to constitute one and the same agreement.

Section 9.16. HIPAA. To the extent applicable, each party agrees to comply with the Health Insurance Portability and Accountability Act of 1996, as codified at 42 U.S.C. § 1320d ("HIPAA") and any current and future regulations promulgated thereunder, including without limitation the federal privacy regulations contained in 45 C.F.R. Parts 160 and 164, the federal security standards contained in 45 C.F.R. Parts 160 and 164, and the federal standards for electronic transactions contained in 45 C.F.R. Parts 160 and 162, all collectively referred to herein as "HIPAA Requirements." The parties agree not to use or disclose any Protected Health Information (as such term is defined in the HIPAA rules and regulations) other than in accordance with HIPAA Requirements and the terms of this Agreement. The parties will make their internal practices, books and records relating to the use and disclosure of Protected Health Information available to the Secretary of the Department of Health and Human Services to the extent required for determining

compliance with HIPAA Requirements. The parties agree to comply with the terms of the Business Associate Addendum which is attached as Annex A hereto and is incorporated herein by this reference.

Section 9.17. Mediation. Any controversy or claim arising out of or relating to this Agreement, including a dispute as to Fees owed, will be settled in the following manner: (a) PROVISION and MTPC will meet to discuss such controversy or claim and use good faith efforts to resolve such controversy or claim; (b) if such controversy or claim is not resolved as contemplated by clause (a), PROVISION and MTPC will, by mutual consent, select an independent third party to mediate such controversy or claim, provided that such mediation will not be binding upon any of the parties; and (c) if such controversy or claim is not resolved within thirty (30) days of the commencement of mediation, it will be resolved in accordance with Section 9.18 below; provided, that business disputes will not be subject to arbitration. Notwithstanding the foregoing, nothing in this Section 9.17 will preclude a party from obtaining injunctive relief in accordance with Section 8.2.

Section 9.18. Arbitration.

(a) Any controversy or claim arising out of or in connection with this Agreement not resolved pursuant to Section 9.17, and not solely relating to a business dispute, will be subject to binding arbitration pursuant to the terms of this Section 9.18.

(b) Forum for arbitration shall be Knoxville, Tennessee.

(c) There shall be one arbitrator. If the parties shall fail to select a mutually acceptable arbitrator within ten (10) business days after the demand for arbitration is mailed, then the parties stipulate to arbitration before a single arbitrator to be selected in accordance with the rules of the American Health Lawyers Association ("AHLA") Dispute Resolution Service.

(d) Disputes hereunder will be submitted to AHLA Dispute Resolution Service and will be conducted in accordance with the rules of the AHLA Dispute Resolution Service.

(e) The arbitrators will be bound by and strictly enforce the terms of this Agreement, and may not limit, expand or otherwise modify its terms. The arbitrators shall make a good faith effort to apply substantive applicable law, but an arbitration decision will not be subject to review because of errors of law. The arbitrators will be bound to honor claims of privilege or work product doctrine recognized at law, but the arbitrators will have the discretion to determine whether any such claim of privilege or work product doctrine applies. The arbitrators shall provide a reasoned basis for the resolution of each dispute and for any award.

(f) Each party will bear its own expenses with respect to arbitration and the parties will share equally the fees and expenses of the AHLA and the arbitrators.

(g) The arbitrators will have power and authority to award any remedy or judgment that could be awarded by a court of law in the State of Tennessee. The award

rendered by arbitration will be final and binding upon the parties hereto, and judgment upon the award may be entered in any court of competent jurisdiction in the United States.

(h) Notwithstanding the foregoing, nothing in this Section 9.18 will preclude a party from obtaining injunctive relief in accordance with Section 8.2.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized officers or representatives effective as of the date first above written.

Provision Proton Centers, LLC

By: _____

Name: _____

Title: _____

**MTPC, LLC d/b/a The Scott Hamilton
Proton Center**

By: _____

Name: _____

Title: _____

Annex A

Business Associate Addendum

This HIPAA Business Associate Agreement (“BAA”) is made part of that certain Management Services Agreement dated as of January 1, 2014 (the “Management Services Agreement”), by and between The Proton Therapy Center d/b/a Provision Center for Proton Therapy (“Entity”) and ProVision Health Partners (“Associate”).

Entity and Associate agree that the parties incorporate this BAA into the Management Services Agreement in order to comply with the requirements of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (“ARRA”) and their implementing regulations set forth at 45 C.F.R. Parts 160 and 164 (the “Privacy and Security Rule”). To the extent Associate is acting as a Business Associate of Entity pursuant to the Service Agreement, the provisions of this BAA shall apply and Associate shall be subject to the penalty provisions as specified by ARRA (42 USC §§ 17931(c), 17934(c)). To the extent Associate is to carry out an obligation of Entity under the Privacy and Security Rule, Associate shall comply with the requirements of the Privacy and Security Rule that apply to Entity in the performance of such obligation.

1. **Definitions.** Capitalized terms not otherwise defined in this BAA shall have the meaning set forth in the Privacy and Security Rule. References to “PHI” mean Protected Health Information created or received by Associate from Entity or on Entity’s behalf.
2. **Uses or Disclosures.** Associate will neither use nor disclose PHI except as permitted or required by this BAA or as Required By Law. Associate will not sell PHI or use or disclose PHI for purposes of marketing or fundraising, as defined and proscribed in the Privacy and Security Rule and ARRA. Associate is permitted to use and disclose PHI:
 - (i) to perform any and all obligations of Associate as described in the Management Services Agreement, provided that such use or disclosure would not violate the Privacy and Security Rule if done by Entity directly;
 - (ii) as otherwise permitted by law, provided that such use or disclosure would not violate the Privacy and Security Rule, if done by Entity directly and provided that Entity gives its prior written consent;
 - (iii) to perform Data Aggregation services relating to the health care operations of Entity;
 - (iv) to report violations of the law to federal or state authorities consistent with 45 C.F.R. § 164.502(j)(1);
 - (v) as necessary for Associate’s proper management and administration and to carry out Associate’s legal responsibilities (collectively “Associate’s Operations”), provided that Associate may only disclose PHI for Associate’s Operations if the disclosure is Required By Law or Associate obtains reasonable assurance, evidenced by a written contract, from the recipient that the recipient will: (1) hold such PHI in confidence and use or further disclose it only for the purpose for which Associate disclosed it to the recipient or as Required By Law; and (2) notify Associate of any instance of which the recipient becomes aware in which the confidentiality of such PHI was breached;

- (vi) de-identify PHI in accordance with 45 C.F.R. § 164.514(b), provided that such de-identified information may be used and disclosed only consistent with applicable law.

In the event Entity notifies Associate of a restriction request that would restrict a use or disclosure otherwise permitted by this BAA, Associate shall comply with the terms of the restriction request.

3. **Information Safeguards.** Associate will maintain appropriate administrative, technical and physical safeguards to prevent use or disclosure of PHI not permitted by this BAA. Associate will also maintain administrative, technical and physical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of electronic PHI in compliance with the Privacy and Security Rule, including the documentation requirements.
4. **Subcontractors and Agents.** Associate will require any of its subcontractors and agents, to which Associate discloses any PHI, to agree to comply with the same privacy and security obligations as Associate with respect to such PHI.
5. **Minimum Necessary.** Associate represents that the PHI requested, used or disclosed by Associate shall be the minimum amount necessary to carry out the purposes of the Management Services Agreement. Associate will limit its uses and disclosures of, and requests for, PHI (i) when practical, to the information making up a Limited Data Set; and (ii) in all other cases subject to the requirements of 45 CFR § 164.502(b), to the minimum amount of PHI necessary to accomplish the intended purpose of the use, disclosure or request.
6. **Obligations of Entity.** Entity shall (i) provide Associate with a copy of the notice of privacy practices that Entity produces pursuant to 45 CFR § 164.520, and Entity shall promptly furnish Associate with copies of any material changes to such notice; (ii) notify Associate of any changes in, or revocation of, permission by an individual to use or disclose PHI, if such changes affect Associate's permitted or required uses or disclosures; (iii) notify Associate of any confidential communication request or restriction to the use or disclosure of PHI affecting Associate that Entity has agreed to in accordance with 45 CFR § 164.522.
7. **Access and Amendment.** Consistent with ARRA and the Privacy and Security Rule, Associate shall permit Entity or, at Entity's request, an individual (or the individual's personal representative) to inspect and obtain copies of any PHI about the individual that is in Associate's custody or control and that is maintained in a Designated Record Set. Associate will, upon receipt of notice from Entity, promptly amend or permit Entity access to amend any portion of PHI so that Entity may meet its amendment obligations under 45 CFR § 164.526.
8. **Disclosure Accounting.** Except for disclosures excluded from the accounting obligation by the Privacy and Security Rule and regulations issued pursuant to ARRA, Associate will record for each disclosure that Associate makes of PHI the information necessary for Entity to make an accounting of disclosures pursuant to the Privacy and Security Rule. Associate will make this information available to Entity promptly upon Entity's request for the period requested, but for no longer than the six (6) years preceding Entity's request for the information (except Associate need not have any information for disclosures occurring before the effective date of this BAA or with respect to disclosures required to be recorded by ARRA, the effective date of the ARRA regulations with respect to Entity).

9. **Inspection of Books and Records.** Associate will make its internal practices, books, and records, relating to its use and disclosure of PHI, available upon request to Entity or the Secretary of U.S. Department of Health and Human Services ("HHS") to determine Entity's compliance with the Privacy and Security Rule.
10. **Reporting.** To the extent known to or discovered by Associate, Associate shall promptly report to Entity any use or disclosure of PHI not permitted by this BAA, any Security Incident involving electronic PHI, and any Breach of Unsecured Protected Health Information involving PHI. Associate shall mitigate, to the extent practicable, any harmful effect known to it of a Security Incident, Breach or use or disclosure of PHI by Associate not permitted by this BAA. Notwithstanding the foregoing, the parties acknowledge and agree that this section constitutes notice by Associate to Entity of the ongoing existence and occurrence of attempted but Unsuccessful Security Incidents (as defined below) for which no additional notice to Entity shall be required. "Unsuccessful Security Incidents" shall include, but not be limited to, pings and other broadcast attacks on Associate's firewall, port scans, unsuccessful log-on attempts, denials of service and any combination of the above, so long as no such incident results in unauthorized access, use or disclosure of electronic PHI. All reports of Breaches shall be made in compliance with 45 CFR § 164.410.
11. **Term and Termination.**
- 11.1. **Term.** This BAA shall be effective as of the effective date of the Management Services Agreement and shall remain in effect until termination of the Management Services Agreement. Either party may terminate this BAA and the Management Services Agreement effective immediately if it determines that the other party has breached a material provision of this BAA and failed to cure such breach within thirty (30) days of being notified by the other party of the breach. If the non-breaching party determines that cure is not possible, such party may terminate this BAA and the Management Services Agreement effective immediately upon written notice to other party. If termination is not feasible, the non-breaching party shall report the breach to HHS.
- 11.2. **Obligations upon Termination.** Upon termination of this BAA for any reason, Associate will, if feasible, return to Entity or destroy all PHI maintained by Associate in any form or medium, including all copies of such PHI. Further, Associate shall recover any PHI in the possession of its agents and subcontractors and return to Entity or destroy all such PHI. In the event that Associate determines that returning or destroying any PHI is infeasible, Associate may maintain such PHI but shall continue to abide by the terms and conditions of this BAA with respect to such information and shall limit its further use or disclosure of such information to those purposes that make return or destruction of the information infeasible.
- 11.3. **Survival.** Upon termination of this BAA for any reason, all of Associate's obligations under this BAA shall survive termination and remain in effect (a) until Associate has completed the return or destruction of PHI as required by Section 11.2 and (b) to the extent Associate retains any PHI pursuant to Section 11.2.
12. **General Provisions.** In the event that any final regulation or amendment to final regulations is promulgated by HHS or other government regulatory authority with respect to PHI, the parties

shall negotiate in good faith to amend this BAA to remain in compliance with such regulations. Any ambiguity in this BAA shall be resolved to permit Entity and Associate to comply with the Privacy and Security Rule. Nothing in this BAA shall be construed to create any rights or remedies in any third parties or any agency relationship between the parties. A reference in this BAA to a section in the Privacy and Security Rule means the section as in effect or as amended. The terms and conditions of this BAA override and control any conflicting term or condition of the Management Services Agreement and replace and supersede any prior business associate agreements in place between the parties. All non-conflicting terms and conditions of the Management Services Agreement remain in full force and effect.

IN WITNESS WHEREOF, the parties have executed this BAA effective as of the date first written above.

ENTITY

**THE PROTON THERAPY CENTER,
LLC
D/B/A PROVISION CENTER FOR
PROTON THERAPY**

BY: _____

NAME: _____

TITLE: _____

ASSOCIATE

**PROVISION HEALTH PARTNERS,
LLC**

BY: _____

NAME: _____

TITLE: _____

A.6 - Site Control

CONTRACT FOR PURCHASE OF REAL ESTATE

THIS CONTRACT FOR PURCHASE OF REAL ESTATE is made and entered into on the dates hereinafter set forth, by and between E. Warner Bass, Trustee (the "Seller") and Amence Development, LLC, or its assigns (the "Purchaser").

WITNESSETH:

1. PROPERTY

Seller, in consideration of the mutual covenants and obligations herein and of the Earnest Money as set forth herein, has this day sold and does hereby agree to convey to Purchaser, and Purchaser agrees to purchase from Seller, at the consideration of the Purchase Price and upon the terms and conditions hereof, the following described real property, hereinafter referred to as the "Property":

That certain tract or parcel of real estate known as Parcel 48.04 on Tax Map 079 in Franklin, Williamson County, Tennessee consisting of approximately 11.6 acres of undeveloped land located on the east side of Carothers Parkway at the intersection of Physicians Way, and being Lot 3 on the Medcore Medical Building Subdivision Final Plat, Revision Two, of record in Plat Book P56, Page 82, Register's Office of Williamson County, Tennessee, together with all appurtenances, rights, privileges, easements, and advantages belonging thereto

2. CONSIDERATION AND PAYMENT

2.1. Subject to the adjustments provided for herein and the other terms and provisions of this Contract, Purchaser agrees to pay, and Seller agrees to accept as full consideration for the conveyance of the Property, an amount equal to Fourteen and One-Half Dollars (\$14.50) per square foot (the "Purchase Price"), payable in cash at Closing, less any Earnest Money and Extension Fees previously paid and accrued interest. In the event the total area of the Property is determined by the Survey to be provided by Purchaser to be more or less than eleven and six-tenths (11.6) acres, then the price shall be adjusted up or down by Fourteen and One-Half Dollars (\$14.50) per square foot multiplied by the difference in square feet.

2.2. Within five (5) business days after full execution of this Contract by both parties, Purchaser shall deposit with Stewart Title Company, attention Mr. Matt Malario (matt.malario@stewart.com) (the "Escrow Agent") the sum of Fifty Thousand Dollars (\$50,000) in cash. Said funds shall serve as Earnest Money for this Contract and shall be held in trust by Escrow Agent and deposited in an FDIC insured money market escrow account subject to the terms and conditions hereof. The Earnest Money and interest accrued thereon shall be fully refundable to Purchaser if (a) the initial Ninety (90) day Inspection Period expires without Purchaser having given written approval of its inspection, or (b) there is a material change in the condition of the Property between the end of the Inspection Period or final Extension Period and date of Closing which is not satisfied by Seller on or before the date of Closing, or (c) the Seller defaults under any terms of the Contract.

FEB 10 '15 PM 2:13

3. SURVEY AND TITLE APPROVAL

3.1. A survey and surveyor's certificate, in form sufficient to remove the survey exception from the title insurance binder as more specifically provided in Paragraph 3.2(a) hereof, will be obtained by Purchaser from a licensed surveyor acceptable to Purchaser within sixty (60) days from the Effective Date hereof. The survey shall be made in accordance with the Minimum Standard Detail Requirements for ALTA/ACSM Land Title Surveys for a Class A survey. Such survey shall show the total area of the Real Property in square feet, easements, if any, location of adjoining streets and rights of way, building setback lines, and such other details as may be required by Purchaser. Once prepared, the survey description will become a part of this Contract identified as Exhibit A - Survey, and such survey description shall be insurable by the title company.

3.2. Within five (5) days from the Effective Date hereof Purchaser shall apply to Stewart Title Company for a title insurance binder in the amount of the Purchase Price which shall constitute the commitment of such company to insure the title to the Real Property in the name of Purchaser with an ALTA owner's title insurance policy. Upon delivery of all required surveys, certificates, and affidavits, the title company shall omit the Standard Exceptions for rights or claims of parties in possession not shown by the public records, for unrecorded easements, for matters which would be disclosed by a survey, and for liens for services, labor or materials.

3.3. Purchaser shall have fifteen (15) business days from its receipt of the title insurance binder, copies of all documents referenced in title exceptions disclosed therein, and the survey within which to review same. If any title defects or other matters objectionable to Purchaser are disclosed by any of the items listed in the previous sentence, Purchaser shall give Seller written notice of same prior to the expiration of such fifteen (15) business day period. Seller shall be allowed a reasonable time, not in excess of fifteen (15) days, within which to cure such defects; provided, however, that in no event shall Seller's cure period extend beyond the Closing Date without the express written consent of Purchaser. If the defects are not timely cured to Purchaser's satisfaction, Purchaser may waive such defects and proceed to close, or Purchaser may terminate this Contract by written notice to Seller, in which event the Earnest Money shall be immediately returned to Purchaser and each of the parties shall be released from further liability to the other.

3.4. At Closing, such title insurance binder, as approved by Purchaser, shall be modified to remove the ALTA Standard Exceptions and any other matters to which Purchaser has objected, to show title to the Property vested in Purchaser, and to update the effective date of such title insurance binder to the Closing Date.

4. CLOSING COSTS

4.1. Purchaser shall pay the following costs and expenses in connection with the transaction contemplated by this Agreement:

- (a) Purchaser's Escrow Agent's fees;
- (b) all transfer and recording fees, costs, and taxes;

- (c) the cost of the Title Report;
- (d) the cost and expenses of the owner's title insurance policy;
- (e) the cost of the Survey; and
- (f) any and all costs incurred by Purchaser in connection with the preparation, review and negotiation of this Agreement and the transactions and the Closing contemplated by this Agreement, including any expenses associated with Purchaser's investigation of the Property, and any attorneys' or consultancy fees.

4.2. Seller shall pay the following costs and expenses in connection with the transaction contemplated by this Agreement:

- (a) Seller's Escrow Agent's fees;
- (b) any fees, costs or taxes related to releases of existing liens;
- (c) Seller's Broker's fees and Purchaser's Broker's fees;
- (d) the cost of preparation of the special warranty deed; and
- (e) any and all costs incurred by Seller in connection with the preparation, review and negotiation of this Agreement and the transactions and the Closing contemplated by this Agreement, including any attorneys' or consultancy fees.

5. ADJUSTMENTS

5.1. Real and personal property ad valorem taxes upon the Property assessed for the year in which Closing occurs, including any rollback taxes for that year, shall be prorated as of the Closing Date. Any back taxes, including rollback taxes, assessed for any year prior to the year in which Closing occurs shall be paid in full by Seller at or prior to Closing, including all delinquent and/or interest charges.

5.2. All other expenses of operating or owning the Property shall be prorated as of the Closing Date, those paid or accruing prior to the Closing Date being Seller's responsibility and those accruing on and after the Closing Date being Purchaser's responsibility.

6. RISK OF LOSS

Seller shall bear the risk of loss or damage to the Property until transfer of title to the Property to Purchaser.

7. CONDEMNATION

7.1. If all or any part of the Real Property is subject to a pending or threatened condemnation or similar proceeding or is otherwise taken through any power of eminent domain prior to Closing, Purchaser may elect to:

(a) Terminate this Contract and have the Earnest Money immediately returned, in which case each of the parties shall be released from further liability to the other, or

(b) Purchase the Real Property under the terms of this Contract, in which event Seller shall assign to Purchaser all of Seller's interest in and to any condemnation award.

7.2. Purchaser's election under the preceding Paragraph 7.1 shall be made in writing to Seller at any time within fifteen (15) days of Purchaser's receipt of Seller's written notice of such taking or pending or threatened condemnation or similar proceeding.

8. CONVEYANCES

At Closing, Seller shall convey, assign and transfer to Purchaser, by such instruments and assignments as may be acceptable to Purchaser good and marketable fee simple title to the Real Property, without exceptions except as expressly provided herein, by a good and valid Special Warranty Deed. Seller shall execute and deliver such other documents and instruments of assignment and transfer as Purchaser may require.

9. INSPECTION PERIOD; DUE DILIGENCE REVIEW

9.1. Purchaser shall have Ninety (90) calendar days from the Effective Date ("Inspection Period") to inspect the Property, review the deed, restrictive covenants, easements and access agreements, any leases, and the title commitment; apply for certificate of need or other jurisdictional approvals, order civil, geotechnical, topographical and environmental reports and perform any other due diligence the Buyer deems necessary including obtaining financing (the "due diligence review"). If Purchaser, in its sole discretion, approves the acquisition of the Property, it shall so notify Seller in writing during the Inspection Period. Failure to give timely written notice of satisfactory inspection shall be deemed disapproval. In such an event, the Earnest Money shall be immediately returned to Purchaser, and each of the parties shall be released from further liability to the other.

9.2. Notwithstanding the generality of the foregoing Paragraph 9.1, Purchaser's tests and investigations during the Inspection Period shall include the following determinations with respect to Purchaser's intended use and development of the Property.

(a) That the subsurface conditions on the Property are satisfactory for such use and development;

(b) That all necessary utilities are at, or are available at, the Property for connection by Purchaser at reasonable tap-in or connection fees;

- (c) That the Property is zoned and/or subdivided to permit Purchaser's intended use;
- (d) That Purchaser shall be able to obtain adequate ingress and egress to the Property from public and private roads and easements;
- (e) That Purchaser shall have attained all required governmental approvals for the development of the Property for such use, including but not limited to certificate of need, site plan approval, drainage plans, landscaping and grading plans, building permits, and utility tap in agreements; and
- (f) That there has been no storage, treatment, disposal, or release of hazardous or toxic substances on the Property.

9.3. Purchaser and Purchaser's agents, employees, and representatives may inspect the Property, and shall have full and unrestricted access and right of entry thereto during the Inspection Period and through the Closing. During the Inspection Period, Purchaser shall have the right to review the deed, restrictive covenants, easements and access agreements, any leases, and the title commitment; apply for certificate of need or other jurisdictional approvals, order civil, geotechnical, topographical and environmental reports and other engineering studies, to be used in the determinations set forth in Paragraph 9.2 and perform any other due diligence the Purchaser deems necessary including obtaining financing (the "Due Diligence Review"). Seller shall cooperate in the execution of all applications and forms required by Purchaser during the Inspection Period.

9.4. Within five (5) days after this Contract is executed, Seller shall furnish Purchaser with copies of the following documents: existing surveys, any leases, existing environmental reports, existing title commitment or policy, copies of any easement or reciprocal access agreements, and any relevant engineering or inspection reports to the extent that any such materials are in Seller's possession, and any correspondence from any municipality or governmental entity affecting the Property within the last twelve (12) months.

9.5. In the event the Property is not zoned to permit the use contemplated by Purchaser, or subdivision is necessary for a variance, or special use permits are required, it shall be the responsibility of the Purchaser to obtain such rezoning, subdivision, variance or special use permits at its sole cost and expense. Seller shall cooperate in every respect in such undertaking and with local authorities to obtain such zoning, subdivision, variance, or special use permits.

9.6. Purchaser, at its sole option, shall have the right to extend the Inspection Period for four (4) additional periods of thirty (30) days each (each an "Extension Period") by delivery to Seller on or before the end of the initial Inspection Period or each of the then-current Extension Periods the sum of Twenty-Five Thousand Dollars (\$25,000) (the "Extension Fee"), along with written notice of Purchaser's election to extend the Inspection Period. The Earnest Money and the Extension Fee(s) shall be non-refundable in the event Purchaser terminates this Contract for any reason whatsoever after the initial Ninety (90) day Inspection Period, but shall be applied to the Purchase Price at Closing if and when Purchaser completes the purchase of the Property.

9.7. Seller acknowledges and consents that the tests and investigations to be conducted by Purchaser during the Inspection Period may result in irrevocable damage or changes to the Property. Notwithstanding such consent, Purchaser agrees to restore the Property to its condition prior to such tests or investigations to the extent it is practicable to do so, and Purchaser agrees to indemnify and hold Seller harmless from all losses, costs and damages due to the failure of Purchaser or its agents, representatives or employees to conduct such tests and investigations with reasonable care in accordance with acceptable commercial, professional, or engineering standards for such tests and investigations.

9.8. Purchaser will provide Seller a copy of any written surveys, engineering and environmental reports and investigations performed by third parties at Purchaser's request.

10. REPRESENTATIONS AND WARRANTIES

10.1. Seller is the true and lawful owner of the Property and has full power and authority to enter into this Contract and to convey the Property. Seller's execution of this Contract and performance hereunder is not in conflict with or a breach or default under any other agreement to which Seller is bound.

10.2. Seller has not received any notice that the Property is not in compliance with any federal, state or local statute, ordinance, rule, regulation, requirement or code, including without limitation health and environmental laws.

10.3. With respect to the operation, use, and ownership of the Property, there is no existing or, to the best of Seller's knowledge, threatened default or dispute under the terms of any agreement or contract which materially and adversely affects the Property or its value.

10.4. There are no encumbrances, liens, or charges of any kind upon the Property which will not be satisfied and discharged in full by Seller and released, at or before the Closing, in form satisfactory to Purchaser.

10.5. There has been no storage, disposal, treatment or release of hazardous substances on the Property during the period of Seller's ownership, and to the best of Seller's knowledge there has been no storage, disposal, treatment or release of hazardous substances during the period prior to Seller's ownership. To the best of Seller's knowledge, no part of the Property is being used, or has ever been used, for any manufacturing, handling or other process involving hazardous substances. The terms as used herein, including but not limited to "hazardous substances," shall have the broadest meaning given under applicable state and federal law.

10.6. All of the covenants, representations, and warranties of the Seller made herein are and shall be continuous and continuing and all of the same shall remain true and correct in all respects through Closing, and all of the same shall survive for a period of six (6) months following the Closing and transfer of title to the Property to Purchaser as contemplated hereunder.

{ Other than easements and other matters reflected on the Survey to be obtained by Purchaser,

End JEP

11. CONTRACT DEFAULT

11.1. If Seller fails to comply with this Contract within the time specified or if Seller breaches any covenant contained herein or if any of Seller's representations and warranties are untrue, Purchaser shall be entitled to the immediate return of the Earnest Money and may pursue any remedies available to Purchaser at law or in equity, including without limitation (i) termination of this Contract and suit for money damages, or (ii) suit for specific performance hereof and money damages. An election by Purchaser to pursue any one or more of its available remedies at law or in equity shall in no way limit or be deemed a waiver of its rights to pursue any other remedies available.

11.2. If Purchaser fails to comply with this Contract within the time specified and Seller does not waive such default, Seller, as Seller's sole and exclusive remedy for such default, shall be entitled to retain the Earnest Money in lieu of Purchaser's obligations to perform hereunder, and Purchaser shall be released of all obligations and liabilities hereunder. Seller expressly waives any right to specific performance of this Contract. Because of the difficulty, inconvenience and uncertainty of ascertaining actual damages for a default by Purchaser, Purchaser and Seller agree that the Earnest Money shall be deemed liquidated damages.

12. CLOSING DATE AND LOCATION

12.1. The Closing shall be held on or before sixty (60) days after the later of expiration of the Inspection Period or final Extension Period, or on such other date as shall be mutually agreeable to Purchaser and Seller.

12.2. The Closing shall be held at such location as is mutually satisfactory to Purchaser and Seller.

12.3. At Closing, the Purchase Price, all documents herein contemplated for the conveyance of the Property, and the payment of the Purchase Price, and all other necessary documents and instruments shall be executed and/or delivered. Possession of the Property shall be transferred to Purchaser on the Closing Date.

13. NOTICES

All notices required herein must be written and shall be deemed to have been validly given when deposited postage prepaid either (i) with a nationally recognized overnight courier or (ii) in the United States Mail, Certified, Return Receipt Requested, addressed to the parties as identified and set forth below:

Purchaser: ATTN: Mr. John G. Patterson
Amence Development, LLC
5847 San Felipe Rd, Suite 2575
Houston, Texas 77057
(281)705-0102
John@Amence.com

Seller: E. Warner Bass, Trustee
150 Third Avenue South
Suite 2800
Nashville, TN 37201
(615)742-6210
wbass@bassberry.com

With a copy to:
Boyce C. Magli
Magli Realty Company
301 Public Square
P.O.Box 448
Franklin, TN 37065

14. AGREEMENT

This Contract constitutes the sole and entire agreement between Purchaser and Seller and no modification hereof shall be binding unless signed by both Purchaser and Seller. Representations, promises, or inducements not included in this Contract shall not be binding upon either of the parties.

15. SUCCESSORS AND ASSIGNS

This Contract shall be binding upon and shall inure to the benefit of each of the parties hereto, their respective heirs, successors, assigns, beneficial owners and representatives. The rights of Purchaser under this Contract shall be freely transferable or assignable by Purchaser, in whole or part, and such assigns of Purchaser shall assume all rights, privileges and obligations of Purchaser hereunder, and shall perform same.

16. OFFER AND ACCEPTANCE

Unless this Contract shall be accepted and executed by Seller on or before January 16, 2015, and Purchaser is notified immediately in writing thereof, this offer shall be null and void. This offer may not be accepted if, prior to Seller's execution hereof, the same shall have been revoked by Purchaser. This offer may be revoked by notice to Seller as provided in Paragraph 13 hereof.

17. COMMISSIONS

Seller agrees to pay to a commission at Closing to Magli Realty Company and Amence Realty, LLC (collectively, the "Brokers") pursuant to a separate agreement between the Brokers and Seller in connection with the purchase and sale of the Property as described in this Contract. Purchaser will not be responsible for any commission payable to Brokers. Seller represents and warrants that Seller will not pay and has not paid any other real estate commission or fees, nor shall any other such commission or fees become due, to any person as a result of the transaction contemplated herein. Seller agrees to save and hold Purchaser harmless from any and all claims made by any agent, broker, or other person engaged by Seller.

18. MISCELLANEOUS

18.1. Time is of the essence in the performance and satisfaction of the obligations and conditions of this Contract.


18.2. Seller shall assist Purchaser as necessary in providing necessary signatures and site information (as the current land owner) for the required permitting and certificate of need ("CON") applications that Purchaser will submit to the required jurisdictional agencies.

18.3. Seller agrees not to disclose any confidential information regarding this transaction to any entities other than the direct owners of the Property, including, without limitation, the name of Purchaser's client/affiliate that will be a tenant/owner of the Property. Seller agrees to keep all information related to application process for the CON confidential.

18.4. At Closing, Seller shall execute a Transferor's Certificate of Non-Foreign Status as required by Section 1445 of the Internal Revenue Code in a form satisfactory to Purchaser.

18.5. The validity, construction, interpretation and performance of this Contract shall, in all ways be governed and determined in accordance with the laws of the State of Tennessee.

18.6. Notwithstanding anything provided herein to the contrary, should either party hereto employ attorneys to enforce any of the provisions hereof, then the party losing in any final judgment agrees to pay to the prevailing party all reasonable costs, charges and expenses, including attorneys' fees expended or incurred in connection therewith.

 ~~18.7. This Contract is governed by, and must be interpreted under, the laws of the State of Tennessee.~~

18.8. Purchaser acknowledges that E. Warner Bass, Trustee is executing this Contract in his capacity as Trustee, and shall have no liability hereunder in excess of the property held by him as Trustee.

18.9. Purchaser acknowledges that Seller, or any beneficiary of Seller, may prefer to exchange part or all of his interest in the Property for other property of like-kind within the meaning of Section

1031 of the Internal Revenue Code, and Purchaser agrees to cooperate with Seller in accomplishing such exchanges.

18.10. This Contract may be signed in counterparts, all of which taken together shall constitute one instrument. A facsimile or email copy will be deemed an original.

gub
~~-(signature page follows)-~~ *gub*

IN WITNESS WHEREOF, this Contract has been executed by the Purchaser and Seller on the dates set out below their respective signatures hereto, the latter of which shall be the Effective Date of this Contract.

PURCHASER

Amence Development, LLC,
a Texas limited liability company

By: *John G. Patterson*

John G. Patterson, Managing Member

Date: January 16, 2015

SELLER

By: *E. Warner Bass*

E. Warner Bass, Trustee

Date: January 16, 2015

Exhibit A

Survey

(to be attached upon completion)

ASSIGNMENT AND ASSUMPTION AGREEMENT

This Assignment and Assumption Agreement (the “**Agreement**”), effective as of January 22, 2015 (the “**Effective Date**”), is by and between Amence Development, LLC, a Texas limited liability company (“**Assignor**”), and MTPC, LLC, a Tennessee limited liability company (“**Assignee**”).

WHEREAS, Assignor has entered into that certain Contract for Purchase of Real Estate (the “**Contract**”) dated January 16, 2015, providing for the purchase of 11.6 acres of undeveloped land located in Williamson County, Tennessee, from E. Warner Bass, Trustee, subject to various terms and conditions all as set forth in greater detail in the Contract, a copy of which is attached hereto as Exhibit A; and

WHEREAS, Assignor desires to assign all of its right, title and interest in and to the Contract, and Assignee desires to assume all of Assignor’s duties and obligations under the Contract.

NOW, THEREFORE, in consideration of the mutual covenants, terms and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Assignment and Assumption. Assignor hereby sells, assigns, grants, conveys and transfers to Assignee all of Assignor’s right, title and interest in and to the Contract. Assignee hereby accepts such assignment and assumes all of Assignor’s duties and obligations under the Contract and agrees to pay, perform and discharge, as and when due, all of the obligations of Assignor under the Contract accruing on and after the Effective Date.

2. Governing Law. This Agreement shall be governed by and construed in accordance with the internal laws of the State of Tennessee without giving effect to any choice or conflict of law provision or rule (whether of the State of Tennessee or any other jurisdiction).

3. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Agreement delivered by facsimile, email or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

4. Further Assurances. Each of the parties hereto shall execute and deliver, at the reasonable request of the other party hereto, such additional documents, instruments, conveyances and assurances and take such further actions as such other party may reasonably request to carry out the provisions hereof and give effect to the transactions contemplated by this Agreement.

(signature page follows)

IN WITNESS WHEREOF, the parties have executed this Assignment and Assumption Agreement to be effective as of the date first above written.

ASSIGNOR:

Amence Development, LLC, a Texas limited liability company

By: 

Name: John G. Patterson

Title: President

ASSIGNEE:

MTPC, LLC, a Tennessee limited liability company

By: 

Name: Michael J. Somers

Title: Secretary

EXHIBIT A

Contract for Purchase of Real Estate

(see attached)

B.II.A. - Square Footage and Costs Per Square Footage Chart

**B.II.E.1. - Fixed Major Medical Equipment -
FDA Approval Documentation**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Sumitomo Heavy Industries, Ltd.
% Mr. Ronald S. Warren
Director, Regulatory Services
11440 W. Bernardo Court, Suite 300
SAN DIEGO CA 92127

November 19, 2013

Re: K130426

Trade/Device Name: Sumitomo Proton Therapy System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: October 29, 2013
Received: October 31, 2013

Dear Mr. Warren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

B.II.E.3 - Major Medical Equipment - Vendor Quotations

Budgetary Quotation

(Ref. No. Budgetary-S001-01)

January 17, 2015

Customer : MTPC, LLC
2095 Lakeside Center, Suite 101,
Knoxville, TN 37922

Attention : Mr. R. Scott Warwick

Subject : Sumitomo Proton Therapy System

Dear Scott Warwick,

Per your request, we, Sumitomo Heavy Industries, Ltd. ("SHI") are pleased to submit a budgetary quotation of one set of **Sumitomo Proton Therapy System** ("PTS") for MTPC, LLC ("Customer"). The system configuration is two rotating gantries and one fixed beam port. The facility site is expected to be in Mid-Tennessee area.

We are hoping this quote meets with your business plan.

Yours sincerely,



Yoshihito Kameda
General Manager, Medical System Sales
Industrial Equipment Div.
Sumitomo Heavy Industries, Ltd.

Budgetary Quotation

(Ref. No. Budgetary-S001-01)

January 17, 2015

1. Quotation

Sumitomo Proton Therapy System 1 set JP¥5,490,000,000-

The scope of the system configuration includes two gantries and one fixed beam port.
The scope of supply is listed in the Attachment hereafter in this quotation.

Notes:

1. The price of the Scope does not include the software (Treatment Planning System and Oncology Information System).
2. The price of the Scope does not include the operation and maintenance of the equipment after taking over.

2. Trade Terms

DAP destination Incoterms ®2010

The destination is in the mid-Tennessee area, such as Nashville. Sumitomo has no obligation to clear the goods for import to the U.S.A., pay any import duties or carry out any import customs formalities. Installation is not included, and shall be discussed when the site is finalized and the site condition becomes clear.

3. Delivery Schedule

Thirty (30) months from the Contract Date

The above schedule of taking over is based on the condition that the Customer prepares the space of storage for the equipment near the installation site. The schedule of taking over shall be reasonably extended in the event that SHI is delayed or impeded by reasons not attributable to SHI.

4. Payment Terms

3.1 Payments shall be made in Japanese yen by the Customer to SHI in accordance with

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Budgetary Quotation

(Ref. No. Budgetary-S001-01)

January 17, 2015

the following manner

(1) The 1st payment as advance payment:

Thirty (30) percent of the total contract price of the PTS ("Contract Price") shall be paid by wire transfer to a bank account to be designated by SHI within thirty (30) days of the Contract Date upon receipt of SHI's invoice. Any banking fee charged by the bank telegraphic transferring/remitting shall be borne by the Customer.

(2) The 2nd payment upon shipment:

Sixty (60) percent of the total Contract Price shall be paid by an irrevocable Letter of Credit ("L/C"), and the L/C shall become payable at sight when SHI presents the shipping documents. In the event of partial shipments, the payment due shall be made on a prorated basis upon each shipment.

(3) The 3rd payment upon taking over:

Ten (10) percent of the total Contract Price shall be paid by an irrevocable L/C, and the L/C shall become payable at sight when SHI presents a certificate of taking over of the PTS. Such certificate of taking over shall be issued immediately after the receipt of the system.

3.2 All of the above L/Cs related to the payments shall be opened by the Customer within thirty days (30) of the Contract Date through a first class international bank acceptable to SHI, and terms of the L/Cs shall be satisfactory to SHI. All costs related to the opening of L/Cs shall be borne by the Customer.

5. Warranty

The warranty period shall start from the date of taking over of the PTS and end at the date of twenty four (24) months from the date of taking over of the PTS.

6. Validity

All of the quotations and conditions shown in this proposal are valid through July 15, 2015.

7. Other Conditions

6.1 Any national, provincial, local, or other taxes, levies, charges, duties and assessments, including customs duties, value added, stamp, withholding, business or

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Budgetary Quotation

(Ref. No. Budgetary-S001-01)

January 17, 2015

sales taxes, or the like, as applicable in the U.S.A. including any ancillary or additional tax hereto, shall be borne by the Customer, and any taxes, levies, charges, duties and assessments of any nature which may be imposed outside the U.S.A. shall be borne by SHI.

- 6.2 Should any withholding tax is imposed in the U.S.A. upon the payments by the Customer to SHI, the Customer shall not withhold any amount payable to SHI. In such event, it is the Customer's responsibility to increase the gross amount of the payment in order not to change the net amount receivable by SHI
- 6.3 Detailed terms and conditions other than the conditions contained herein shall be specified at the time of the Contract.

Budgetary Quotation

(Ref. No. Budgetary-S001-01)

January 17, 2015

Attachment

Scope of Supply for Three (2) Compact Gantries and one (1) Fixed beam port

Scope of Supply (1/8)

No.	Items	Q'ty	MTPC	Sumitomo
100	Accelerator System			
110	230 MeV Cyclotron	1 set		✓
120	Energy Selection System (ESS)	1 set		✓
130	Beam Transport System (BTS)	1 set		✓
200	Gantry Treatment System			
210	Gantry System			
211	Rotating Gantry (Compact Type 360deg)	2 sets		✓
212	Gantry Beam Transport System	2 sets		✓
220	Nozzle			
221	Pencil Beam Scanning Nozzle	OPTION		
222	Multi-purpose Nozzle	2 sets		✓
223	On-line PET System	OPTION		
224	Multi-leaf Collimator	OPTION		
230	Patient Support System			
231	Robotic Patient Positioning System (Including Treatment Couch)	2 sets		✓
232	Indexed Body Frame System for Patient Fixture	2 sets		✓
233	Head / Neck / Skull Slope Base	2 sets		✓
240	Treatment Set-up and Verification Imaging System			
241	Laser Marker for Patient Positioning (5 per treatment room)	2 sets		✓
242	Digital Radiography (DR) System (Biplane)	2 sets		✓
243	Respiration Gating System	OPTION		
244	Function of CBCT	OPTION		

Note:(1) ✓ mark indicates the party who is responsible for each item

(2) (✓) mark indicates the party who supports the other party.

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Budgetary Quotation

(Ref. No. Budgetary-S001-01)

January 17, 2015

Scope of Supply (2/8)

No.	Items	Q'ty	MTPC	Sumitomo
250	QA Tools for Gantry			
251	Standard Water Phantom (with Data Format transferable to TPS)	2 sets		✓
252	Gantry Water Phantom	2 sets		✓
253	Standard Dosimeter	2 sets		✓
254	2D-array Ion Chamber	1 set		✓
255	Build-up Polyethylene Blocks for Dose Measurement	2 sets		✓
256	Film Dosimetry System	1 set		✓
257	Patient Dose QA Phantom	1 set		✓
300	Fixed Beam Port			
310	Beam Transport System for Fixed Beam Port			
311	Beam Transport System	1 set		✓
320	Nozzle			
321	Multi-purpose Nozzle	1 set		✓
330	Patient Support System			
331	Robotic Patient Positioning System (Including Treatment Couch)	1 set		✓
332	Indexed Body Frame System for Patient Fixture	1 set		✓
333	Head / Neck / Skull Slope Base	1 set		✓
340	Treatment Set-up and Verification Imaging System			
341	Laser Marker for Patient Positioning	1 set		✓
342	Digital Radiography (DR) System (Monoplane)	1 set		✓
350	QA Tools for Experimental Port			
351	Standard Dosimeter	1 set		✓
352	Build-up Polyethylene Blocks for Dose Measurement	1 set		✓

Note:(1) ✓ mark indicates the party who is responsible for each item

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Budgetary Quotation

(Ref. No. Budgetary-S001-01)

January 17, 2015

Scope of Supply (3/8)

No.	Items	Q'ty	MTPC	Sumitomo
400	Treatment Control System	1 set		✓
500	Power Supply System			
510	Power Supply System			
511	Power Supply Unit	1 set		✓
512	UPS for Server System and PC	1 set		✓
513	Power Distribution Panel	1 set		✓
514	Electrical Power Distributors for each Room and	1 set		✓
515	AC Power Line from Cubicle to Power Distributors	1 set	✓	
516	De-ionized Water Cooling System	1 set		✓
600	Sub-Systems			
610	Treatment Planning System			
611	Treatment Planning System	TBD	✓	
620	Oncology Information System	TBD	✓	
630	Record and Verification System	3 sets		✓
640	Simulator System			
631	CT Simulator	OPTION		
632	MRI Simulator	OPTION		
633	Respiration Gating System for CT Simulator	OPTION		

Note:(1) v mark indicates the party who is responsible for each item

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Budgetary Quotation

(Ref. No. Budgetary-S001-01)

January 17, 2015

Scope of Supply (4/8)

No.	Items	Q'ty	MTPC	Sumitomo
640	Compensator and Collimator Fabrication System			
641	Compensator Fabricating System (Milling Machine)	OPTION		
642	Collimator Fabricating System (Wire Cut Machine)	OPTION		
643	3D Measurement System	OPTION		
644	CAD/CAM system	1 set		✓
650	Safety System for PTS Building			
651	Radiation Monitoring Systems (Sensors and Central process unit)	1 set	✓	
652	Door Interlock and Confirmation buttons for each room	1 set	✓	
653	Display for each Room Entrance (Design will be provided by SHI)	1 set	✓	
654	Shield Plugs and Doors	1 set	✓	
655	Wiring from Radiation Monitoring System to the PTS	1 set	✓	
656	Wiring from Door interlock switches, safety buttons and Displays to the PTS	1 set	✓	
657	Integration Work for Interlock of Radiation Safety	1 set		✓
700	Off Site Engineering			
710	Site Planning			
711	Layout Plan			✓
712	Detailed Design of the Building Structure, Electrical System, Air Conditioning System, and Other Utilities		✓	
713	Check and Review of Drawings (PTS area)			✓
714	Radiation Shielding Design (Radiation data will be provided by SHI)		✓	(✓)

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Budgetary Quotation

(Ref. No. Budgetary-S001-01)

January 17, 2015

Scope of Supply (5/8)

No.	Items	Q'ty	MTPC	Sumitomo
800	Engineering at site			
810	Transportation and Storage			
811	From Supplier's Factory to the U.S.A. Port			✓
812	Unloading from Ship to Bonded Warehouse			✓
813	Customs Clearance		✓	
814	Inland Transportation			✓
815	Preparation of the Storage Area before and during Installation		✓	
816	Security of Storage Area		✓	
820	Installation and Assembly			
821	Check the Building condition prior to Installation		✓	(✓)
822	If necessary, Adjusting Building based on SHI's instruction before Construction. The Drawing of the Building shall be checked and confirmed by SHI and Customer together.		✓	(✓)
823	Check the Building Drawings (before Construction)			✓
824	Installation, Assembly and Alignment of the System		✓	
825	Preparation of Site Office Space		✓	
826	Truck Crane for Installation		✓	
827	Buried Line for Wiring and Water in the Wall		✓	
828	Piping Material for Water, Gas, Air etc. from Supply Source to Interface Point		✓	
829	Supervision of Installation Work			✓
830	Wiring Work and Piping Work		✓	
831	Preparing Alignment Tools		✓	
832	Cables (Power Cables, Control Cables) and Connectors			✓
833	Cable Tray		✓	

Note: (1) ✓ mark indicates the party who is responsible for each item

(2) (✓) mark indicates the party who supports the other party.

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Budgetary Quotation

(Ref. No. Budgetary-S001-01)

January 17, 2015

Scope of Supply (6/8)

No.	Items	Q'ty	MTPC	Sumitomo
836	Wiring Check and Electricity Test			✓
837	Piping Pressure Test and Flashing Work		✓	
838	Benchmarks for the Alignment of the System		✓	
839	Base Plates and Plates Set-up for Installation of Cyclotron, Gantries and Couches (Drawing will be provided by SHI)		✓	
840	Base Plates Adjustment before Filling Concrete			✓
841	Filling Concrete		✓	
842	Anchor Bolts, Shim Plates and Templates for Anchor Bolts Setting			✓
843	Electricity and Water for Installation		✓	
844	Insurance for Labors and Equipment		✓	
850	Tuning			
851	Tuning the System			✓
852	Quality Checking and Adjustment			✓
853	Electricity, City Water, Air Conditioning, Compressed Air and N2 Gas for Tuning		✓	
854	Operators for Tuning and Test Operation			✓
855	Measuring Devices, Testing Equipment and Tools		✓	(✓)
860	Acceptance Test			
861	Acceptance Testing			✓
862	Witness and Issuance of the Acceptance Certificate		✓	

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Budgetary Quotation

(Ref. No. Budgetary-S001-01)

January 17, 2015

Scope of Supply (7/8)

No.	Items	Q'ty	MTPC	Sumitomo
870	Training			
871	On-site Training			✓
872	Training at SHI Factory in Japan			✓
873	Arrangement of Training at NCCH in Japan			✓
874	Airfare, Domestic Traveling and the Costs of Accommodations of the Customer's Personnel during Training		✓	
875	The Other Costs related to Customer's Personnel		✓	
876	The Other Costs related to SHI's Personnel			✓
900	Maintenance and Warranty			
910	Documents			
911	Operation Manuals (Including Manuals for all sub-contractor's Equipment)	3 sets		✓
912	Maintenance Manuals (in English)	3 sets		✓
913	Assembly Drawings	3 sets		✓
914	Electrical Wiring Diagrams	3 sets		✓
920	Replacement Parts and Spare Parts			
921	Replacement Parts and Spare Parts required for Commissioning and Testing before Taking Over			✓
922	Replacement Parts during Warranty Period, and the relevant Spare Parts in case of failure during the Warranty Period			✓
924	Replacement / Spare Parts List			✓
925	Clinical Consumables for Treatment (i.e. Materials of collimators and compensators, patient fixture device specific to each patient, etc.)		✓	(✓)

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Budgetary Quotation

(Ref. No. Budgetary-S001-01)

January 17, 2015

Scope of Supply (8/8)

No.	Items	Q'ty	MTPC	Sumitomo
930	Warranty			
931	12 Months from the Date of Taking Over			✓
940	Maintenance during warranty period			
941	Maintenance services			✓
942	Operation service for PTS		✓	
1000	Building Construction			
1001	Site Preparation, Civil Work, Building Construction for the Proton Therapy System	1 set	✓	
1002	Utilities (Power, Dry N ₂ Gas, Air Compressor with Air Drier, City Water)	1 set	✓	
1003	City Water Circulating Cooling System	1 set	✓	
1004	Power Transformer, ACB and Cubicle 440V AC	2 sets	✓	
1005	Cable Connection to the Distribution Panel	2 sets	✓	
1006	Air Conditioning System	1 set	✓	
1007	Lighting in the Building	1 set	✓	
1008	Embedded I-beam for Geared Trolley (Accelerator Room)	1 set	✓	
1009	Deck for Gantry Maintenance	2 sets		✓
1010	Hoist Cranes (Accelerator Room, BT Room, Experimental room and Gantry Room)	3+3 sets	✓	
1011	Telephone, Intercom and Paging System in PTS Area	1 set	✓	
1012	Other Equipment required by Local Regulations (such as Automatic Sprinkler System)	1 set	✓	

Note:(1) ✓ mark indicates the party who is responsible for each item

(2) (✓) mark indicates the party who supports the other party.

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Budgetary Quotation

(Ref. No. Budgetary-S002-01)

January 17, 2015

Customer : MTPC, LLC
2095 Lakeside Center, Suite 101,
Knoxville, TN 37922

Attention : Mr. R. Scott Warwick

Subject : Service on Sumitomo Proton Therapy System

Dear Scott Warwick,

Per your request, we, Sumitomo Heavy Industries, Ltd. ("SHI") are pleased to submit a budgetary quotation of services for **Sumitomo Proton Therapy System** ("PTS") for MTPC, LLC ("Customer"). The system configuration is two rotating gantries and one fixed beam port. The facility site is expected to be in Mid-Tennessee area.

We are hoping this quote meets with your business plan.

Yours sincerely,



Yoshihito Kameda
General Manager, Medical System Sales
Industrial Equipment Div.
Sumitomo Heavy Industries, Ltd.

Budgetary Quotation

(Ref. No. Budgetary-S002-01)

January 17, 2015

1. Quotation for 5-year Service

	Maintenance Service	Operation Service	Total
1 st year (Warranty Period)	(Included in the PTS contract)	\$589,000.00-	\$589,000.00-
2 nd year	\$2,200,000.00-	\$605,000.00-	\$2,805,000.00-
3 rd year	\$2,600,000.00-	\$439,000.00-	\$3,039,000.00-
4 th year	\$2,100,000.00-	\$448,000.00-	\$2,548,000.00-
5 th year	\$3,250,000.00-	\$457,000.00-	\$3,707,000.00-
Total	\$10,150,000.00-	\$2,538,000.00-	\$12,688,000.00-

The above prices are based on the following conditions:

- a) The PTS operates for 254 days a year from Monday to Friday with 16-hour daily operation time consisting of 2-hour morning start-up, 12-hour treatment time, and 2-hour QA after daily treatment.
- b) The PTS has two (2) sets of a rotating gantry with a multi-purpose nozzle. This Service quotation is based on the scope of supply described in the Equipment Quotation of Sumitomo Proton Therapy System (Doc. No. Budgetary-S001-01).
- c) The Maintenance Services consist of:
 - (1) Daily Maintenance,
 - (2) Weekly Maintenance,
 - (3) Annual Maintenance,
 - (4) Trouble shooting.
- d) Service Team consists of seven (7) persons in total. For the first two years, Japanese service engineers station at the site, and from the third year onwards, all service personnel will be locally hired.
- e) Parts are categorized in Replacement Parts and Spare Parts. The Replacement Parts are scheduled to replace according to the operation time. The Spare Parts are classified into three types as follows:

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Budgetary Quotation

(Ref. No. Budgetary-S002-01)

January 17, 2015

- (1) S-A : stored on site
 - (2) S-B : stored in SHI's US local service center
 - (3) S-C : stored in SHI's factory in Japan
- f) Update and/or upgrade and/or renewal of computer systems is not included in the Service, and will take place on Customer's request with charge.
- g) Replacement of the flat panel detectors for all DR systems is scheduled in every 5 years, and their costs are included in the maintenance service in the 5th year.
- h) Maintenance Service does not include the annual maintenance service fee of Treatment Planning System (TPS) and Oncology Information System (OIS), which have not been specified yet and are not included in the scope of supply of the equipment quotation.
- i) Maintenance Service does not include update and upgrade of TPS and OIS, which will take place on Customer's request with charge. The costs for the update and the upgrade of other software will be agreed through negotiation when Customer requests the update and/or the upgrade of the software.
- j) The costs of consumables such as compensators and collimators for individual patients are not included in this quotation.
- k) The costs of utilities such as electricity, water, gas, etc. required for maintenance work shall be supplied by Customer without charge.

2. payment Terms

- 25 % Payment in cash at three (3) months time after the start of each Service year,
- 25 % Payment in cash at six (6) months time after the start of each Service year,
- 25 % Payment in cash at nine (9) months time after the start of each Service year,
- 25 % Payment in cash at twelve (12) months time after the start of each Service year.

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(Ref. No. Budgetary-S002-01)

January 17, 2015

3. Warranty

Warranty includes materials of the parts and workmanship of Sumitomo engineers for 3 months after completion of maintenance works.

4. Validity

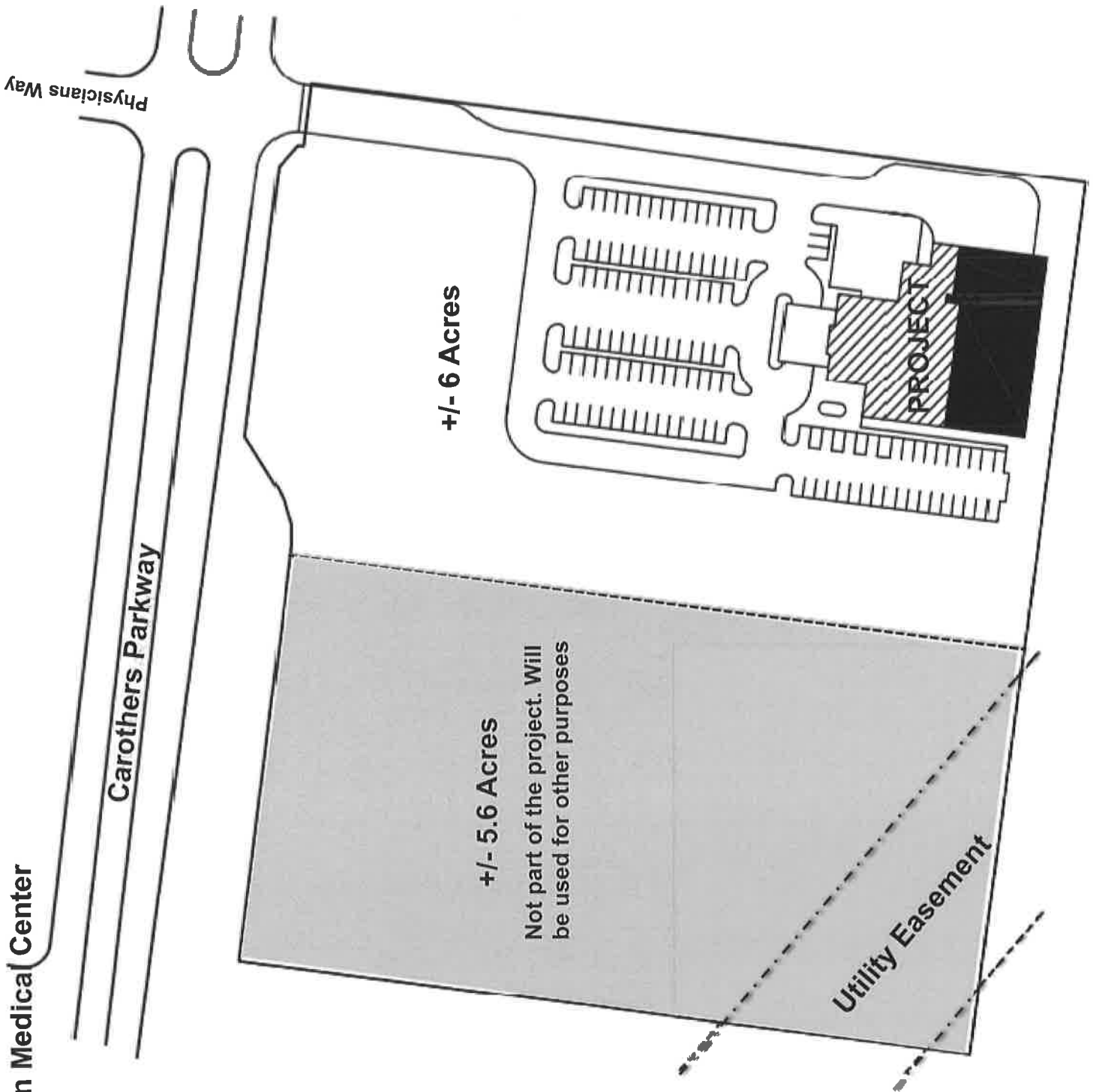
The quotation shown in this proposal is for reference purpose only which is based on the current costs of materials, equipment, personnel charges, currency conditions, transportations, accommodations etc., and shall be revised at the time of the contract negotiation for the Services. The actual yearly prices are determined by negotiation every year before the service year starts.

5. Other Conditions

- 5.1 Any federal, state, local, or other taxes, levies, charges, duties and assessments, including customs duties, value added, stamp, withholding, business or sales and use taxes, or the like, as applicable in the U.S.A. including any ancillary or additional tax hereto, shall be borne by the Customer, and any taxes, levies, charges, duties and assessments of any nature which may be imposed outside the U.S.A. shall be borne by SHI.
- 5.2 Should any withholding tax is imposed in the U.S.A. upon the payments by the Customer to SHI, the Customer shall not withhold any amount payable to SHI. In such event, it is the Customer's responsibility to increase the gross amount of the payment in order not to change the net amount receivable by SHI
- 5.3 Detailed terms and conditions other than the conditions contained herein shall be specified at the time of the Contract. SHI shall not be liable for any loss of profit, loss of use, loss of production or for any other indirect or consequential damages.

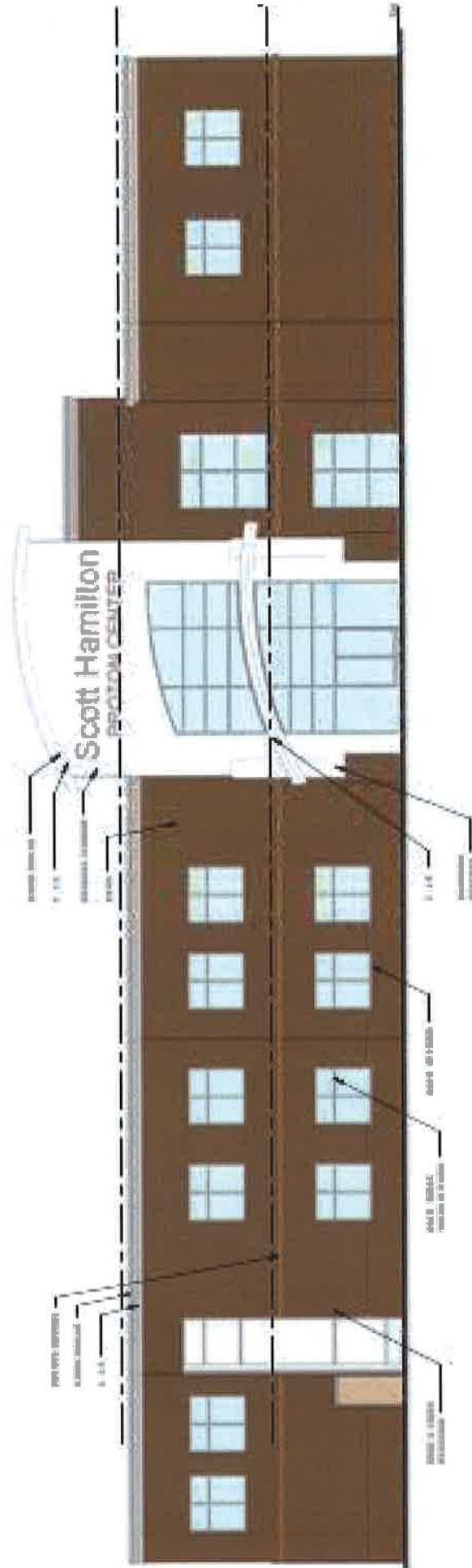
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B.III. - Plot Plan



B.IV. - Floor Plan

Scott Hamilton Proton Center

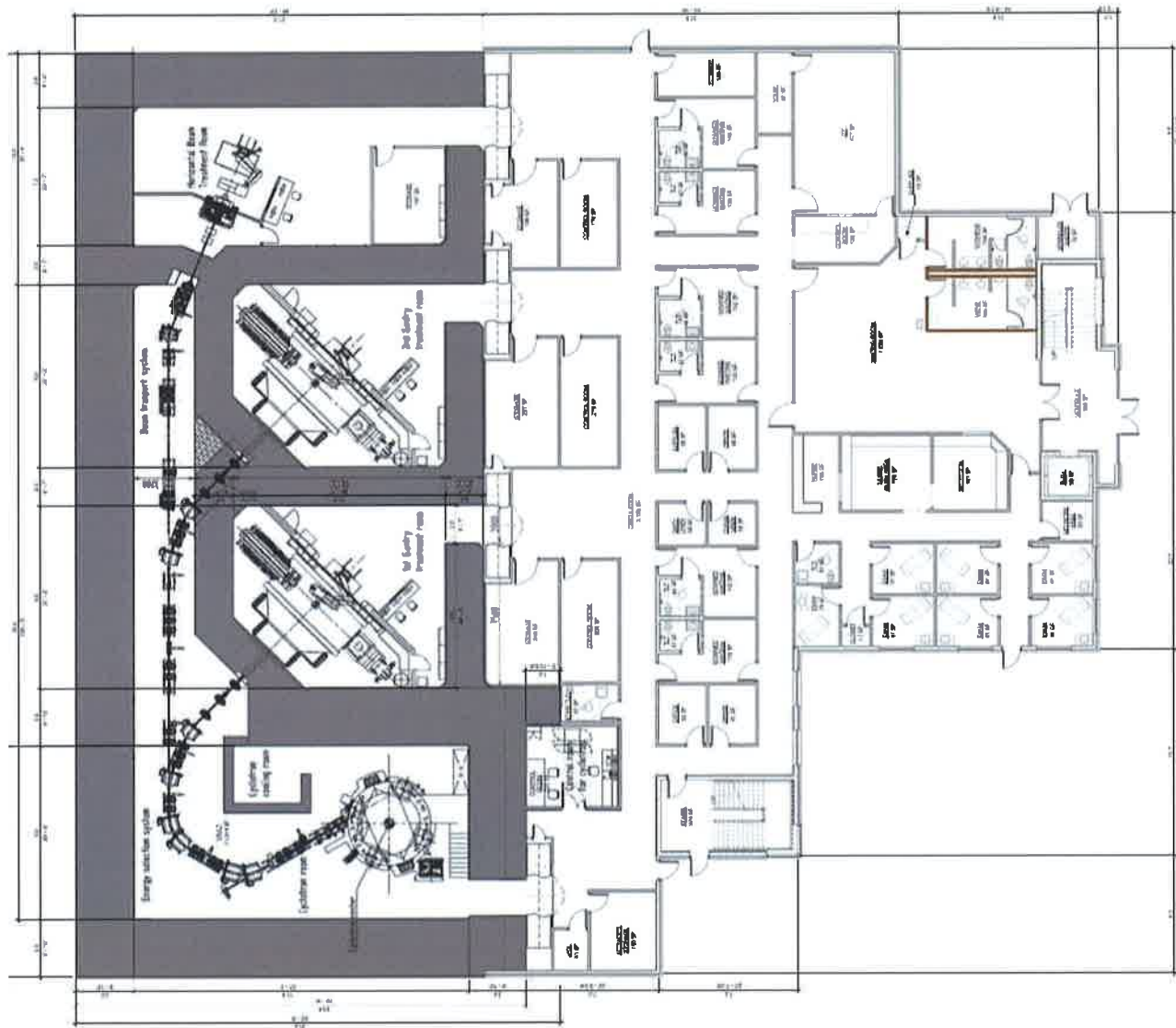


OCCUPANCY		
ROOM #	ROOM NAME	Area
101	WAITING ROOM	1,036 SF
102	MENS	166 SF
103	WOMENS	166 SF
104	SPRINKLER WATER	72 SF
106	CONTROL ROOM	132 SF
108	CT	477 SF
116	CONTROL ROOM	203 SF
117	CONTROL ROOM	223 SF
128	EXAM	91 SF
129	EXAM	91 SF
131	EXAM	91 SF
132	EXAM	91 SF
133	MD WORK AREA	59 SF
134	ELEV.	58 SF
135	RECEPTION	161 SF
136	NURSE WORK AREA	198 SF
137	CLEAN LINEN	58 SF
138	DIRTY LINEN	58 SF
142	GOWNED WAITING	133 SF
143	TLT	46 SF
144	STAIRS	274 SF
146	JAN.	41 SF
202	BREAK ROOM	437 SF
203	LARGE MEETING ROOM	798 SF
204	ELEC.	239 SF
205	OFFICE	116 SF
206	IT	165 SF
207	OFFICE	118 SF
208	OFFICE	124 SF
209	OFFICE	118 SF
210	OFFICE	122 SF
211	OFFICE	118 SF
212	SUPPLIES / COPY	61 SF
213	JAN.	53 SF
214	OFFICE	111 SF
216	OFFICE	120 SF
217	TREATMENT PLANNING	423 SF
218	PHYSICS	404 SF
219	WOMEN	173 SF
220	MEN	173 SF
221	PARTS	481 SF
222	CIRCULATION	1,372 SF
224	CLOSET	43 SF
225	OFFICE	119 SF
227	ELEV. EQUIP.	62 SF
229	OFFICE	88 SF
233	EQUIP.	81 SF
234	ELEV.	58 SF
236	SUPPLIES	88 SF
238	SUPPLIES	18 SF
239	CONTROL ROOM	215 SF
241	OFFICE	107 SF

OCCUPANCY		
ROOM #	ROOM NAME	Area
244	SERVICES / STORAGE	610 SF
248	ACTIVATED STORAGE	150 SF
257	SUPPLY	112 SF
259	OFFICE	110 SF
264	GOWNED WAITING	133 SF
265	GOWNED WAITING	142 SF
266	TLT	46 SF
267	TLT	37 SF
268	STORAGE	123 SF
270	EXAM	91 SF
271	EXAM	91 SF
272	EXAM	79 SF
273	TLT.	51 SF
274	GOWNED WAITING	133 SF
275	GOWNED WAITING	142 SF
276	TLT	46 SF
277	TLT	37 SF
278	OFFICE	82 SF
279	OFFICE	81 SF
280	NURSE	106 SF
281	CIRCULATION	3,192 SF
282	GOWNED WAITING	142 SF
283	TLT	37 SF
284	STAFF TLT.	61 SF
285	CLOSET	17 SF
286	OFFICE	118 SF
287	RESEARCH	118 SF
288	RESEARCH	133 SF
289	STORAGE	81 SF
290	STAFF TLT	49 SF
293	STAIRS	274 SF
294	STAIRS	143 SF
295	OPEN AREA	331 SF
296	CONFERENCE ROOM A1	282 SF
297	LARGE CONFERENCE	284 SF
298	PHYSICS OFFICE	128 SF
299	CONTROL ROOM	178 SF
300	STORAGE	197 SF
301	STORAGE	189 SF
302	STORAGE	257 SF
303	STORAGE	248 SF
304	BILLING	202 SF
305	KITCHEN	232 SF
1000	VAULT	11,514 SF
1001	VESTIBULE	366 SF
MSR	SHARED SERVICES ROOM	1,127 SF
N/A	UNUSABLE	2,237 SF
PSR	POWER SUPPLY ROOM	1,018 SF
		36,083 SF

Scott Hamilton Proton Center

1st Floor



FEB 10 '15 04:2:14

1st Floor – Shielded Treatment Rooms



1st Floor – Medical Office Space

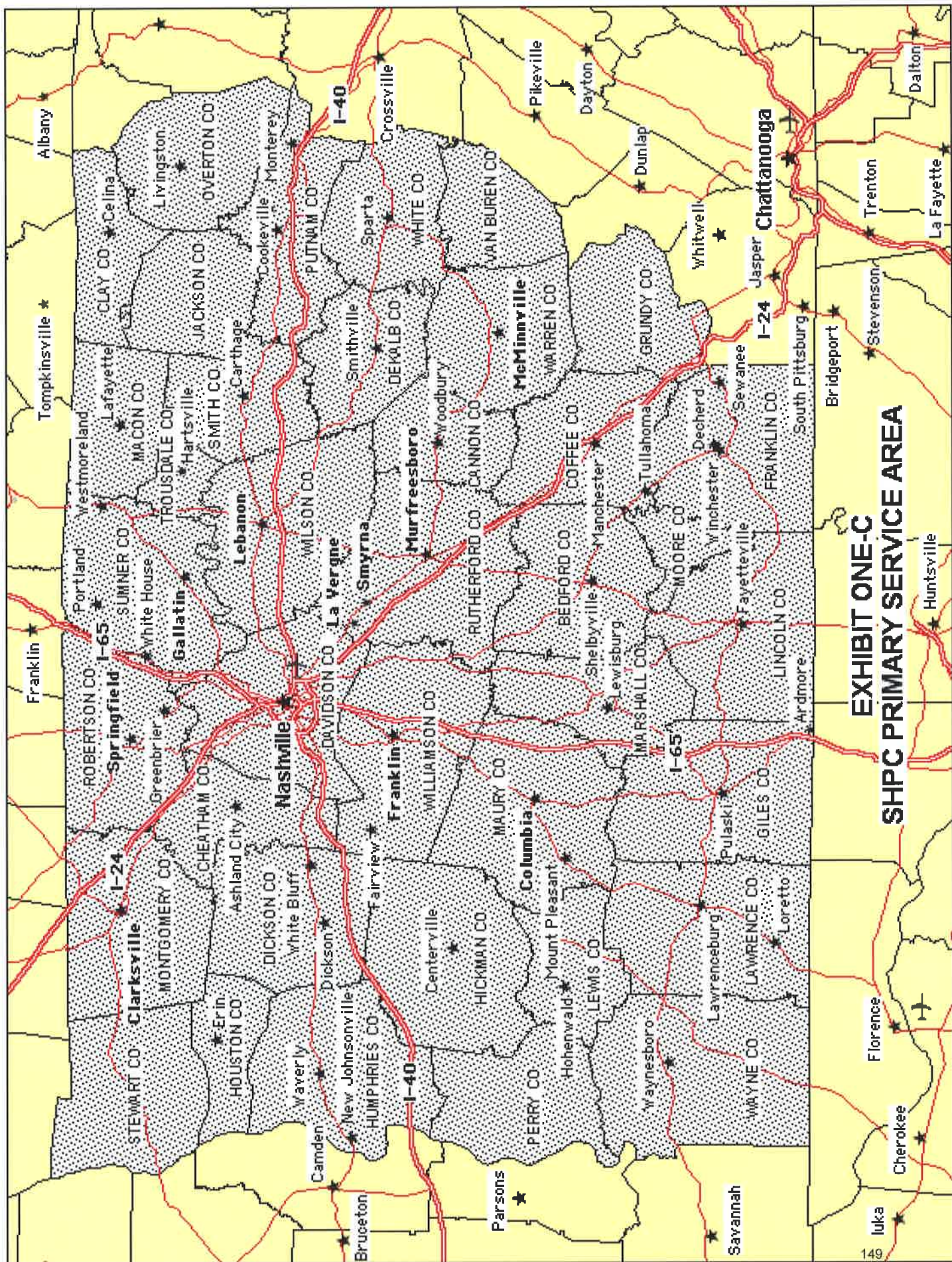


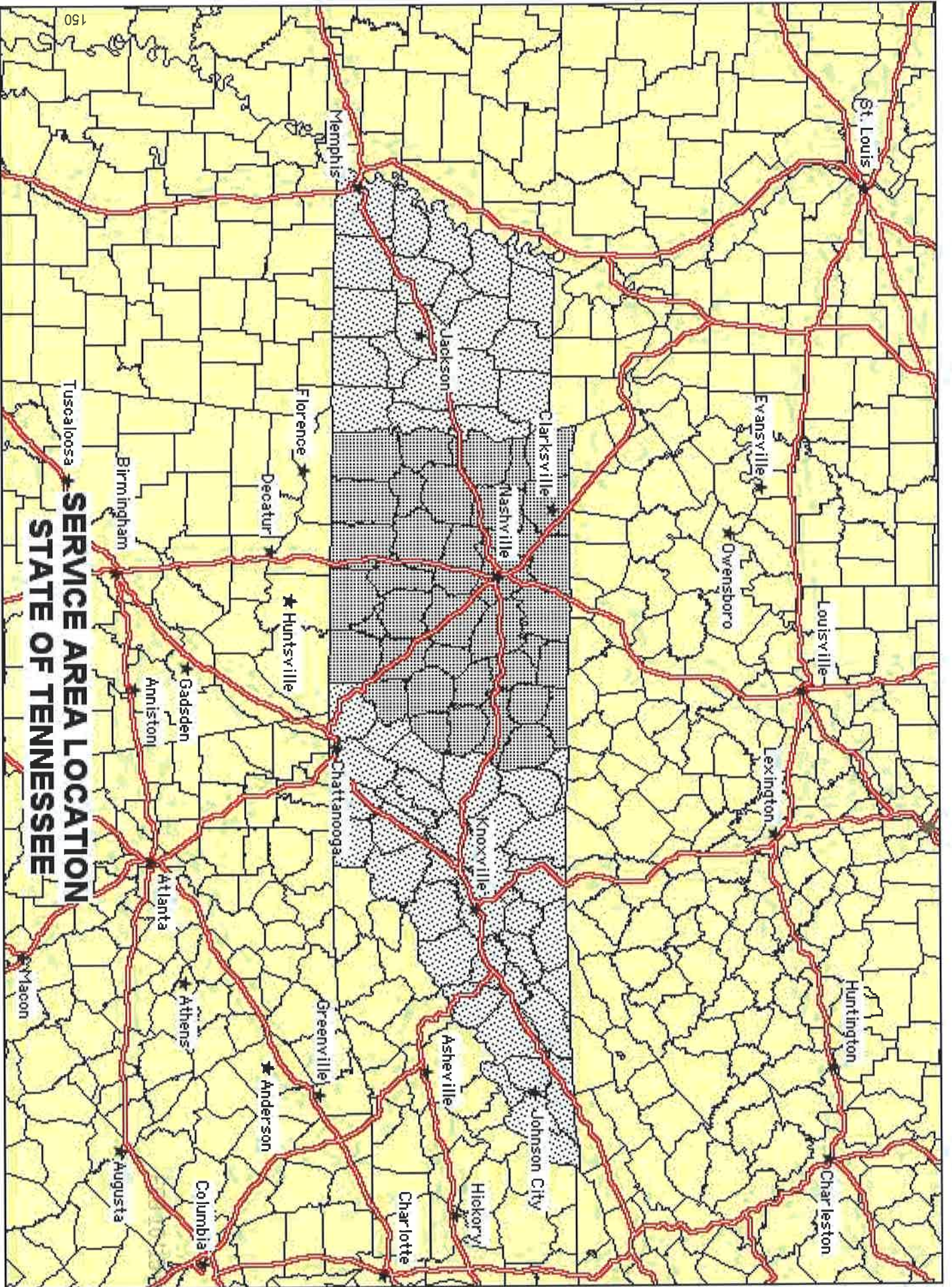
Architectural floor plan of the first floor. The plan includes the following rooms and areas:

- Left Wing:** 2nd Security Treatment room, 1st Security Treatment room.
- Central Wing:** RECEPTION, RESTROOM, A-10 (Corridor), A-11, A-12, A-13, A-14, A-15, A-16, A-17, A-18, A-19.
- Right Wing:** KITCHEN, DINING, LIVING, STAIR, PARKING.

Dimensions are provided for various rooms and corridors, such as 10' 0" x 10' 0", 12' 0" x 12' 0", 14' 0" x 14' 0", etc.

C. Need-3 - Service Area Maps





**SERVICE AREA LOCATION
STATE OF TENNESSEE**

**C. Economic Feasibility-1 - Documentation of
Construction Cost Estimate**

February 9, 2015

Mr. Scott Warwick
MT PC, LLC
2095 Lakeside Centre Way
Suite 101
Knoxville, TN 37922

Re: Scott Hamilton Proton Center
Nashville Tennessee

Dear Mr. Warwick:

We have reviewed the construction cost estimate provided by Merit Construction Inc. for the proposed Proton Therapy Center. Based upon our experience and knowledge of the current construction market, it is our opinion that the project cost of \$17,370,127.39 is a reasonable estimate for a 36,083 square foot Proton Therapy Center.

Below is a summary of building codes and regulations anticipated to be enforced for this project. This listing may not be entirely inclusive, but the intent is for all applicable codes and regulations being enforced by State and Local agencies at the time of plans submitted to be addressed during the design process.

- Guidelines for the Design and Construction of Health Care Facilities
- Rules of Tennessee Department of Health Board of Licensing Health Care Facilities
- Locally Adopted International Building, Mechanical, Plumbing, Gas Codes, and Energy Codes
- National Electrical Code
- National Fire Protection Code (NFPA)
- Americans with Disabilities Act (ADA) and ANSI A117.1

By separate transmittal we will be forwarding to you preliminary floor plans of the proposed Proton Therapy Center for inclusion into your CON (Certificate of Need) submittal. Please contact me if there are any questions.

Sincerely,

Michael Brady Inc.



Brian Pierce, AIA

Principal

Chattanooga
2034 Hamilton Place Blvd., Suite 250
Chattanooga, TN 37421
423-305-5773

Knoxville
299 North Weisgarber Road
Knoxville, TN 37919
865-584-0999

www.michaelbradyinc.com

Cookeville
370 B Reagan Street
Cookeville, TN 38501
931-644-2122

**C. Economic Feasibility-2 - Documentation of
Availability of Funding**



Deutsche Bank

Deutsche Bank Securities Inc.
Global Markets

60 Wall Street
New York, New York 10005

Telephone: 1-212-250-8257

December 23, 2014

State of Tennessee
Health Services and Development Agency
Andrew Jackson Building
500 Deadrick Street, 9th Floor
Nashville, TN 37234

Dear Sir or Madam:

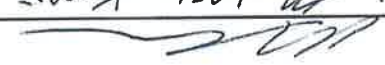
Deutsche Bank Securities Inc. ("we" or "Purchaser") is delivering this letter of intent to purchase the tax-exempt Bonds referenced herein in connection with the submission of the Borrower of its application for a certificate of need for a proton therapy center to be financed with the proceeds of the Bonds. The description of the Bonds is as follows:


Issuer: The Industrial Development Board of Williamson County, Tennessee
Maximum principal amount of bonds: \$110,000,000.00
Borrower: MTPC LLC

In connection with your consideration of the Borrower's application for a certificate of need, we hereby advise you that we have made a commitment to purchase or place the Bonds upon delivery by the issuer for our own account, for the account of others, or for resale. Such commitment is subject to the satisfaction of certain conditions, including, but not limited to, determination of interest rate at or about the time of closing, final forms of documents, instruments, certificates and other documents satisfactory to Purchaser and its counsel; receipt of satisfactory legal opinions; satisfaction of state and federal requirements with respect to the obligations; and no adverse factual or legal changes prior to closing. We shall only have a legally binding obligation with respect to the purchase and sale of the Bonds upon the execution of definitive documentation approved by Purchaser.

Sincerely yours,

DEUTSCHE BANK SECURITIES, INC.

By: 
Name: Michael Kowal
Title: Director

By: 
Name: Michael Kowal
Title: Vice President

Confidential

PRELIMINARY BOND RESOLUTION

WHEREAS, MTPC, LLC, a Tennessee limited liability company (the "Applicant"), is considering the acquisition, construction and equipping of a healthcare facility (the "Project") in Williamson County, Tennessee and wishes to have the Industrial Development Board of Williamson County, Tennessee (the "Board") indicate its willingness to issue revenue bonds to provide financing for such facility; and

WHEREAS, such facility would constitute a "project" within the meaning of T.C.A. § 7-53-101; and

WHEREAS, a letter of intent has been presented to the Board under the terms of which the Board agrees, subject to the provisions of such agreement, to issue its revenue bonds in an amount not exceeding \$110,000,000 to provide financing for such project.

NOW, THEREFORE, BE IT RESOLVED BY THE INDUSTRIAL DEVELOPMENT BOARD OF WILLIAMSON COUNTY, TENNESSEE as follows:

1. The Board hereby finds that the financing of such project will improve the quality of healthcare in Williamson County, Tennessee, and will contribute to the general welfare of the citizens of the County.

2. The Chairman or the Vice Chairman of the Board is hereby authorized to execute a letter of intent with the Applicant in substantially the form thereof as presented to this meeting or with such changes therein as shall be approved by the Chairman or the Vice Chairman. The officers of the Board are hereby authorized to take such further action as is necessary to carry out the intent and purposes of the letter of intent as executed.

3. The Chairman, the Vice Chairman or Legal Counsel of the Board is hereby authorized to conduct such public hearings on behalf of the Board as the Applicant may request with respect to the project.


Approved and adopted this 15th day of January, 2015.

BOARD:

INDUSTRIAL DEVELOPMENT BOARD OF
WILLIAMSON COUNTY, TENNESSEE

By: 
Gayle Moyer Harris, Chairman

ATTEST:


Dan Parsons, Secretary

January 15, 2015

MTPC, LLC
6450 Provision Cares Way
Knoxville Tennessee 37909

Gentlemen:

The Industrial Development Board of Williamson County, Tennessee (the "Board") has been informed that MTPC, LLC, a Tennessee limited liability company (the "Applicant"), is considering the acquisition, construction and equipping of a healthcare facility in Williamson County, Tennessee (the "Project"). The above-described acquisition, construction and equipping with regard to such facility will constitute a "project" within the meaning of T.C.A. § 7-53-101.

After investigation of the nature of the proposed project, the Board has determined that the financing of the project will improve the quality and availability of healthcare in Williamson County and will contribute to the general welfare of the citizens of the County. Therefore, it is the belief of the Board that in assisting the financing of the project, the Board will be acting in furtherance of the public purposes for which it was created.

Accordingly, in order to assist the Applicant to acquire, construct and equip the project and in order to carry out the purposes for which the Board was created, the Board hereby makes the following proposals:

1. The Board will issue, and sell to a purchaser to be designated by the Applicant prior to issuance, revenue bonds (the "Bonds") in the principal amount not to exceed \$110,000,000 to provide financing for the project. The Bonds shall be a limited obligation of the Board payable solely out of the revenues and receipts derived from the project including loan payments from the Applicant obtained in connection with the financing of the project. In no event shall the Bonds be a general obligation of the Board, its directors, or Williamson County.

2. The terms of the Bonds (maturity schedule, interest rate, denominations, redemption provisions, etc.) will be determined by agreement among the Board and the Applicant, subject to compliance with all applicable state and federal requirements, and all bylaws and policies of the Board.

3. Prior to delivery of the Bonds, the Board and the Applicant will enter into a loan agreement pursuant to which the proceeds from the sale of the Bonds will be used for the purposes hereinabove indicated and the Applicant will be obligated to make payments sufficient to cover all debt service requirements on the Bonds.

4. The Board will enter into a trust indenture with a trustee to be nominated by the Applicant and subject to the approval of the Board and/or a purchase contract with the purchaser of the Bonds. Such indenture and/or purchase contract will assign the loan agreement and all collateral therefor and all revenues received thereunder for the benefit of the bondholders. The terms and provisions of such indenture and/or purchase contract shall be agreed upon by the Board, the Applicant and the purchaser of the Bonds.

5. The Board hereby authorizes the Applicant to commence the acquisition, construction and equipping of the project as soon as practicable so that the inhabitants of the State of Tennessee might

benefit from the project without delay. The Applicant may advance any interim funds required and be reimbursed from the proceeds of the Bonds, to the extent allowed by applicable law.

6. Upon the issuance, sale and delivery of the Bonds, the provisions of this proposal and the agreement resulting from its acceptance by the Applicant shall have no further effect and, in the event of any inconsistencies between the terms of this proposal and the terms of any loan agreement and/or indenture or purchase contract the provisions of such latter documents shall control.

7. If for any reason the Bonds have not been sold within one (1) year from the date hereof, the provisions of this proposal and the agreement resulting from the acceptance by the Applicant shall, at the option of either party to be evidenced in writing, be canceled and neither party shall have any rights against the other and no third party shall have any rights against either party except:

(a) The Applicant will pay the Board for all expenses incurred by the Board in connection with the financing of the project;

(b) The Applicant will pay the out-of-pocket expenses paid by the Board's attorneys incurred in connection with the project and will pay reasonable legal fees of the Board's attorneys for the legal services related to the project; and

(c) The Applicant will indemnify and hold the Board harmless against any liability which may be incurred by the Board with respect to the project.

[Remainder of Page Intentionally Left Blank]

If the foregoing proposal is satisfactory to you, you may indicate by signing the following acceptance and returning a copy to the Board. This proposal and your acceptance will then constitute an agreement in principal with respect to the matters herein contained.

Yours very truly,

INDUSTRIAL DEVELOPMENT BOARD OF
WILLIAMSON COUNTY, TENNESSEE

By: 
Title: Chairman

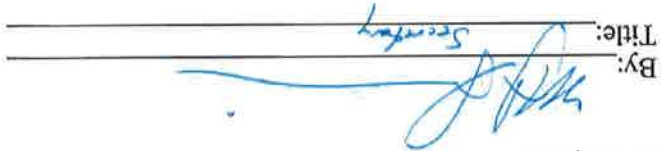
ACCEPTANCE OF PROPOSAL
OF
INDUSTRIAL DEVELOPMENT BOARD OF WILLIAMSON COUNTY, TENNESSEE

BY

MTPC, LLC

The terms and conditions contained in the foregoing proposal by the Industrial Development Board of Williamson County, Tennessee are hereby accepted by MTPC, LLC, this 15th day of January, 2015.

MTPC, LLC

By: 
Title: Secretary

13843536.1

C. Economic Feasibility-10 – Financial Statements

MTPC, LLC
Operating Statement
January 2015

Jan 15	
Income	0.00
Dividend Income	0.00
Unrealized Gain (Loss)	0.00
Realized Gains (Losses)	0.00
Total Income	0.00
Expense	50,000.00
Land Option	50,000.00
Total Expense	50,000.00
Net Income	-50,000.00

MTPC, LLC
Balance Sheet
As of January 31, 2015

EB 03 PM 2-12

ASSETS		Jan 31, 15
Current Assets		
Cash & Cash Equivalents	100,000	
Total Current Assets	100,000	
Marketable Securities	0	
Other Assets	0	
TOTAL ASSETS	100,000	
LIABILITIES & EQUITY		
Equity		
Beginning Fund Balance	150,000	
Net Income	-50,000	
Total Equity	100,000	
TOTAL LIABILITIES & EQUITY	100,000	



State of Tennessee

Health Services and Development Agency

Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243

www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

March 2, 2015

Scott Warwick, Vice President
MTPC
6450 Provision Cares Way
Knoxville, TN 37909

RE: Certificate of Need Application -- Scott Hamilton Proton Center - CN1502-004

To establish a proton therapy center for cancer patients, acquire major medical equipment and initiate outpatient proton therapy services in a new building to be constructed at an unaddressed site containing approximately 11.6 acres located on the east side of Carothers Parkway between its intersection with Physician's Way and Williamson Medical Center in Franklin (Williamson County), TN. Project cost is \$109,057,664.00.

Dear Mr. Warwick:

This is to acknowledge the receipt of supplemental information to your application for a Certificate of Need.

Please be advised that your application is now considered to be complete by this office. Your application is being forwarded to the Tennessee Department of Health and/or its representative for review.

In accordance with Tennessee Code Annotated, §68-11-1601, et seq., as amended by Public Chapter 780, the 60-day review cycle for this project will begin on March 1, 2015. The first sixty (60) days of the cycle are assigned to the Department of Health, during which time a public hearing may be held on your application. You will be contacted by a representative from this Agency to establish the date, time and place of the hearing should one be requested. At the end of the sixty (60) day period, a written report from the Department of Health or its representative will be forwarded to this office for Agency review within the thirty (30)-day period immediately following. You will receive a copy of their findings. The Health Services and Development Agency will review your application on May 28, 2015.

Scott Warwick, Vice President
6450 Provision Cares Way
March 2, 2015
Page 2

Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. § 68-11-1607(d):

- (1) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.
- (2) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have questions or require additional information, please contact me.

Sincerely,

A handwritten signature in dark ink, appearing to read "Melanie M. Hill". The signature is fluid and cursive, with the first name "Melanie" being more prominent than the last name "Hill".

Melanie M. Hill
Executive Director

cc: Trent Sansing, CON Director, Division of Health Statistics



State of Tennessee

Health Services and Development Agency

Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243

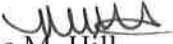
www.tn.gov/hsda

Phone: 615-741-2364

Fax: 615-741-9884

MEMORANDUM

TO: Trent Sansing, CON Director
Office of Policy, Planning and Assessment
Division of Health Statistics
Andrew Johnson Tower, 2nd Floor
710 James Robertson Parkway
Nashville, Tennessee 37243

FROM: 
Melanie M. Hill
Executive Director

DATE: March 2, 2015

RE: Certificate of Need Application
Scott Hamilton Proton Center - CN1502-004

Please find enclosed an application for a Certificate of Need for the above-referenced project.

This application has undergone initial review by this office and has been deemed complete. It is being forwarded to your agency for a sixty (60) day review period to begin on March 1, 2015 and end on May 1, 2015.

Should there be any questions regarding this application or the review cycle, please contact this office.

Enclosure

cc: Scott Warwick, Vice President

LETTER OF INTENT -- HEALTH SERVICES & DEVELOPMENT AGENCY

The Publication of Intent is to be published in the Tennessean, which is a newspaper of general circulation in Williamson County, Tennessee, on or before February 7, 2015, for one day.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. Sections 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that The Scott Hamilton Proton Center (a facility for outpatient proton cancer therapy), to be owned by MTPC, LLC (a limited liability company) and to be managed by Provision Proton Centers, LLC (a limited liability company), intends to file an application for a Certificate of Need to establish a proton therapy center for cancer patients, to acquire major medical equipment (proton therapy equipment and related components), and to initiate outpatient proton therapy services, at an unaddressed site in Franklin (Williamson County). The site is on the east side of Carothers Parkway, between the Parkway's intersection with Physicians Way and Williamson Medical Center. The project cost is estimated at \$106,000,000. The project does not contain any other type of major medical equipment or initiate or discontinue any other health service; and it will not affect any facility's licensed bed complements.

The anticipated date of filing the application is on or before February 11, 2015. The contact person for the project is Scott Warwick, Vice President, MTPC, 6450 Provision Cares Way, Knoxville, TN 37909, 865-684-2613.

R. Scott Warwick 2/4/15 swarwick@pvhealthcare.com
(Signature) (Date) (E-mail Address)

Supplemental #1 -COPY-

Scott Hamilton Proton
Therapy Center

CN1502-004

February 24, 2015**2:49 pm**

February 24, 2015

Jeff Grimm
HSDA Examiner
Tennessee Health Services and Development Agency
9th Floor, 502 Deaderick Street
Nashville, TN 37243

RE: Certificate of Need Application CN1502-004
Scott Hamilton Proton Therapy Center

Dear Mr. Grimm:

This letter responds to your recent request for additional information on this application. The items below are numbered to correspond to your questions. They are provided in triplicate, with affidavit.

1. Section A, Applicant Profile, Items 3 and 4

Please provide an organization chart which shows the ownership and business relationships between MTPC, LLC, the management company, the real estate development company, the financing entities and any other companies within the Provision family of companies. Please also identify all members of MTPC, LLC with ownership interests of 5% or greater

MTPC, LLC expects to enter a management agreement with Provision Proton Centers, LLC, a for-profit LLC.

MTPC, LLC has entered an agreement with Amence Development, LLC, an unrelated real estate development company, to assist the applicant in identifying appropriate property, negotiating the purchase and assisting in the development.

MTPC, LLC is engaging Deutsche Bank Securities, an unrelated financial services firm, to underwrite and/or place the tax-exempt bonds that will be issued to finance the project.

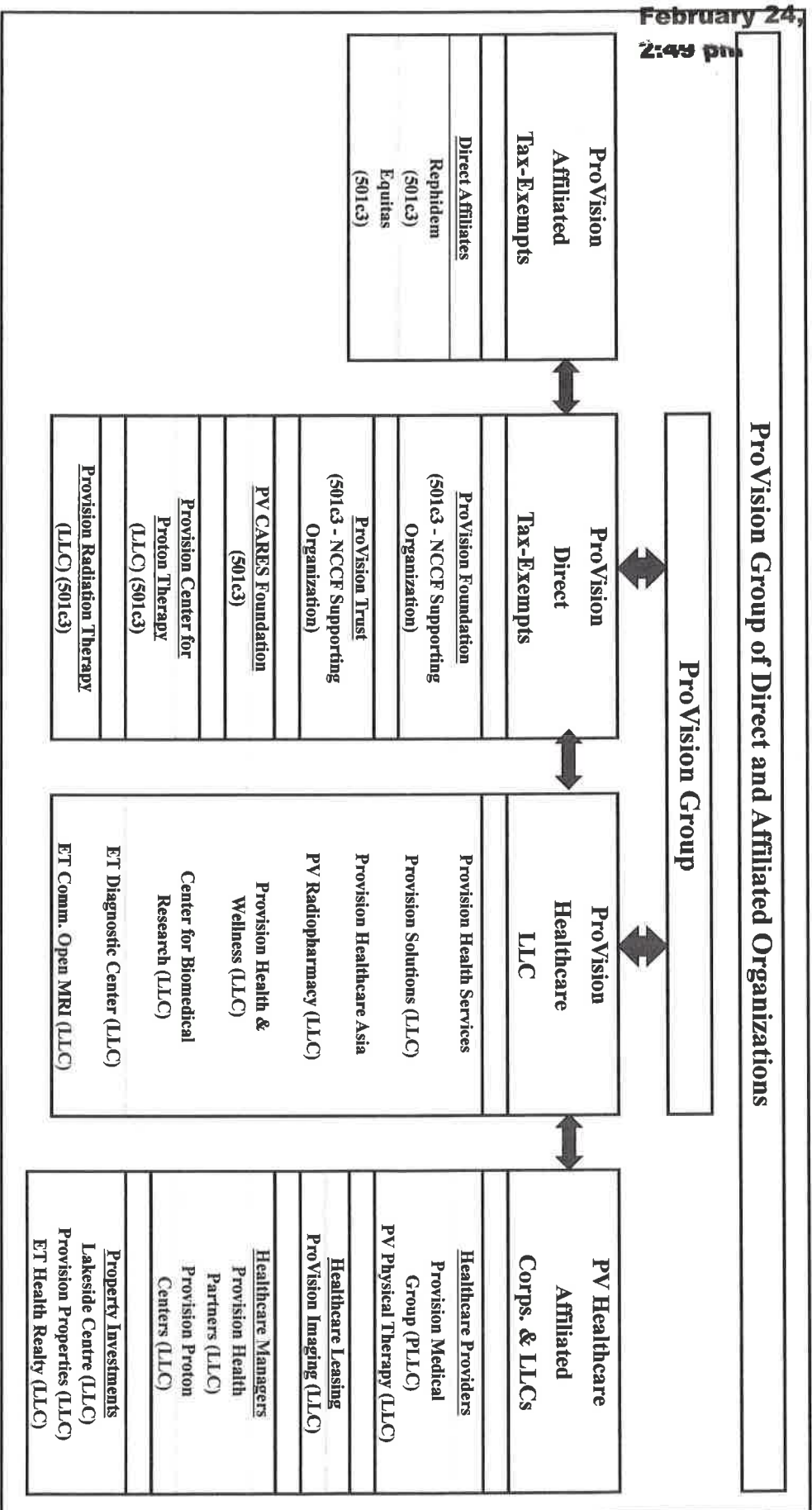
MTPC, LLC has three tax-exempt, not-for-profit members – Provision Trust, Inc. (48%), Scott Hamilton CARES Foundation, Inc. (26%) and Provision CARES Foundation, Inc. (26%). All three entities are public charities so the concept of ownership does not apply.

An organization chart showing the various entities within the Provision Group is submitted following this page.

February 24, 2015

2:49 pm

Pro Vision Group of Direct and Affiliated Organizations



2. Section A, Applicant Profile, Item 5

Your response is noted. Please briefly describe the background and experience of the management company and its executives in proton beam therapy, including the manager's participation in the operation of the new proton center approved and implemented in CN1002-010A.

Staffing for the project has not yet been determined. However, the following individuals are expected to provide leadership and training and otherwise participate in the development and initial operation of the facility on an employed or consulting basis:

Terry Douglass, Ph.D. Dr. Douglass is the Chairman of the Board of the Provision Center for Proton Therapy and has played an integral role in its founding and development. Dr. Douglass has previously served as the Chairman of the Board of CTI Molecular Imaging, Inc., a public company that specialized in the development, production and distribution of products and services for the medical diagnostic imaging market from 1983 to 2005 when it was acquired by Siemens at a market capitalization of \$1 billion. He also served as President and Chief Executive Officer ("CEO") of CTI Molecular Imaging from its formation in 1983 until 2003. During this tenure, Dr. Douglass played an integral role in the development and commercialization of positron emission technology ("PET") and its development globally, including PET cyclotron technology that now plays a significant role in proton therapy. He was also instrumental in the development of Medicare reimbursement for PET services. From 1968 to 1983, Dr. Douglass was employed at EG&G Ortec, where he served as President during the last three years of service. Dr. Douglass is currently leading the development of the world-class comprehensive cancer care program in the Provision Health Alliance at Dowell Springs.

Tom Welch. Mr. Welch is the current President of the Provision Center for Proton Therapy and Provision Proton Centers, LLC. Mr. Welch has more than 20 years of broad business experience from pre-revenue Companies to growth stage and Fortune 50. Mr. Welch was the President and CEO of ABT Molecular Imaging, Inc. starting in 2009, where he led the Company's efforts to turn a technology vision into reality with \$8m in revenue its third year of commercial operations leading to product installations on four continents. He also raised over \$15m in debt and equity through preferred equity and venture debt which, combined with the growth in revenue, facilitated quadrupling the Company value in four years. Prior to joining ABT, Mr. Welch was the CEO of PETNET Solutions, Inc., formerly a division of CTI Molecular Imaging, Inc. and now Siemens Medical Solutions, Inc. Mr. Welch helped PETNET grow from 12 to over 50 radio-pharmacies in his 11 years with PETNET through acquisitions as well as organic growth to become the world's largest manufacturer and distributor of PET radiopharmaceuticals. Several of the PETNET locations were joint ventures with leading healthcare institutions in the United States.

Mr. Welch completed his undergraduate work in Business Administration with a Major in Accounting and follow-on graduate work at the University of Tennessee, receiving his MBA in 2005.

Mary Lou DuBois. Ms. DuBois served as the President of the Provision Center for Proton Therapy during the development and start-up phase and is presently the President of Provision Solutions, LLC which provides start-up, development and value added services to companies that are either developing, operating or considering the development of proton therapy centers. Ms. DuBois was previously employed by CTI Molecular Imaging, Inc. ("CTI") for 20 years and served in various roles. Most recently, Ms. DuBois

served as an Officer and Vice President, Customer Solutions, at CTI, where she led the product management group and was responsible for the coordination and launching of new technology product releases and marketing material to the sales team. She also coordinated and planned trade shows and exhibits for CTI at such shows as the Radiological Society of North America and Society of Nuclear Medicine. Ms. DuBois also led a development team to develop an internet-based customer solutions strategy to differentiate CTI from the competition. She also developed and led CTI's Customer Training Center for PET providers to gain knowledge and entry into the PET market. As Senior Director, Corporate Solutions (Information Technology) for five years, she was responsible for all corporate systems, computers, communications, support and new technology for CTI. Ms. DuBois received her bachelor's degree in business from Tennessee Wesleyan College.

Christopher T. Brown. Mr. Brown is the Chief Financial Officer for Provision Healthcare and has served as the Chief Financial Officer of The Provision Center for Proton Therapy as well as the various provider entities at Provision Health Alliance, including Provision Radiopharmacy, The Provision Health and Wellness Center, Provision Physical Therapy, and the Center for BioMedical Research. Mr. Brown successfully spearheaded the effort to finance the Provision Center for Proton Therapy. Mr. Brown was previously employed at SunTrust Bank from May 2004 to July 2008, Crowe Chizek CPA firm from July 2000 to May 2004, and the Arthur Andersen CPA firm from January 1998 to July 2000. Mr. Brown is a Certified Public Accountant in the State of Tennessee. He received his bachelor's and master's degrees in accounting from the University of Tennessee.

David Raubach. Mr. Raubach is the Vice President of Operations at the Provision Center for Proton Therapy. Prior to joining Provision in July, 2013,

Mr. Raubach spent four years at ProCure Treatment Centers, Inc. While at ProCure he served as the financial and business manager for the Oklahoma City proton center, assisted in the development and start-up of the Seattle and Chicago ProCure proton therapy centers, and served as the practice manager for the ProCure physician group, Oklahoma Proton Radiation Oncology Group. He brings a strong focus on lean healthcare operations as well as expertise in the areas of reimbursement and process management. David graduated with an MBA from Oklahoma State University in 2008 and B.A. in History from the University of Oklahoma in 2006.

Andries "Niek" Schreuder, M.Sc. DABR. Niek Schreuder is the Chief Medical Physicist at the Provision Center for Proton Therapy. Mr. Schreuder is recognized as one of the premier proton therapy trained medical physicists in the world. He came to Provision after serving almost 8 years in the same role for ProCure Treatment Centers, which has opened and operates more proton therapy centers than any other entity. Prior to joining ProCure, Mr. Schreuder was the Director of Medical Physics at the Midwest Proton Radiotherapy Institute in Bloomington, Indiana, home to the United States' third proton therapy center. Among other things, Mr. Schreuder played a critical role in securing FDA approval and commissioning the fixed beam treatment room.

Susan Stinnett. Susan Stinnett is the Director of Clinical Operations at the Provision Center for Proton Therapy. She has been a radiation therapist for 18 years and a clinical leader for 6 years. She decided in high school that her career path would lead to caring for oncology patients. Susan is a member of the American Society of Radiologic Technologists and is certified through the American Registry of Radiologic Technologists. She received her bachelor's degree from Tusculum College in Greeneville, TN.

Scott Warwick. Mr. Warwick is the Vice President of Program Development and Strategic Initiatives for Provision Healthcare and was part of the core team that brought the Provision Center for Proton Therapy from a vision to a clinical reality. Mr. Warwick has more than 18 years of comprehensive cancer program management experience. During his career he has successfully managed the opening of a comprehensive cancer center and the successful merger of two large health systems' multi-site comprehensive cancer programs with over \$25 million in annual revenues. He has also developed and managed oncology joint ventures and created an oncology leadership program for the 14 cancer centers within Catholic Health Partners, one of the largest non-profit health systems in the United States, serving four states with over 100 organizations and 34 hospitals.

Mr. Warwick is a Certified Medical Dosimetrist and has served as an oncology consultant in the finance industry and for educational institutions. Mr. Warwick also serves on the board of several non-profit organizations, including the National Association of Proton Therapy, The Proton Therapy Consortium (PTC), the American Cancer Society Knoxville metropolitan region and serves as the Chair of the PTC Clinical Research Committee. He is a member of the American Association of Healthcare Executives and the American Association of Medical Dosimetrists. Mr. Warwick has a B.S. in Education from the University of Tennessee and graduated from the Allied Health program at the Vanderbilt University School of Radiation Therapy.

Bill Hansen. As Vice President of Business and Strategic Development Mr. Hansen has been responsible for business and strategic planning, marketing and public relations for the Provision Center for Proton Therapy. He has over twenty years of experience in business and marketing management with U.S. and international market experience. He has also provided comprehensive

marketing, product development and sales direction in his previous positions. Prior to joining Provision, Bill was responsible for strategic planning and marketing for IBA, a Belgium company and the current leader in the development of proton therapy equipment. Before joining IBA, Bill spent 10 years at Colle + McVoy in Minneapolis, Minnesota, where he was an advertising strategic planner for multiple clients, including IBA, Medtronic, 3M and Pfizer. Prior to his move to Minnesota, Bill spent 11 years in Silicon Valley where he was a Business Unit Manager for KLA-Tencor, a semiconductor equipment manufacturer in San Jose, CA. Bill holds a BSEE degree from DeVry Institute and an MBA from Santa Clara University.

3. Section A, Applicant Profile, Item 6

Please provide documentation of ownership of the unaddressed 11.6 acre site for the proposed facility as described in the 1/16/2015 signed real estate purchase agreement on page 103 of the application (parcel 48.04, Williamson County tax map 079). Please briefly describe the relationship between the seller (trustee noted in document) and the owner of record of the property.

Public records reflect that the property was conveyed to E. Warner Bass, Trustee by Warranty Deed dated February 17, 1981 from Third National Bank in Nashville, Executor and Trustee under the Will of Agnes Bennett, Trustee of record in Book 383, Page 636 Register's office for Williamson County. A copy of the Warranty Deed is submitted following this page.

February 24, 2015

This instrument prepared by Milton W. Smith, Jr.
2400 Crestmoor Road, Nashville, Tennessee

WARRANTY DEED

BOOK 383 Pg. 636

ADDRESS NEW OWNER (S) AS FOLLOWS:	SEND TAX BILLS TO	MAP PARCEL NUMBERS
E. Warner Bass, Trustee	E. Warner Bass, Trustee	Map 79
(NAME)	c/o Bass, Berry & Sims	Part of Parcel s.
(STREET ADDRESS OR ROUTE NUMBER)	First American Center	48 & 49
(CITY) (P. O. ZONE) (STATE)	Nashville, TN 37258	
	(CITY) (ZONE) (STATE)	

FOR AND IN CONSIDERATION of the sum of Ten and 00/100
----- (\$10.00) ----- Dollars.

Cash in hand paid by the Grantee, hereinafter named, and other good and valuable consideration, the receipt of which is hereby acknowledged.

Third National Bank in Nashville, Executor and Trustee under the Will of Agnes Bennett, Trustee, with full power to sell and convey,

have this day bargained and sold, and do hereby transfer and convey unto the said E. Warner Bass, Trustee, with full power to sell, mortgage, convey, or otherwise encumber without the joinder of any beneficiary, his

certain real estate in Davidson County, Tennessee, as follows:

Williamson

(SEE ATTACHED LEGAL DESCRIPTION)

The terms and conditions of the contract signed by the Grantor and Grantee herein regarding the sale of the property described herein, dated January 14, 1981, and the amendment thereto, dated January 14, 1981, shall survive the closing of this sale.

STATE OF TENNESSEE COUNTY OF DAVIDSON	The actual consideration or value whichever is greater, for this transfer is 440,000.00
Subscribed and sworn to before me, this 17 day of February 19 81	Affiant Campbell Brown
My commission expires 14 JAN 20 1985	Notary Public C. M. Miller

This is improved () property, known as Highway 96 and Curd Lane, Franklin, Tennessee
(House Number) (Street) P. O. Address (City or Town)

TO HAVE AND TO HOLD said real estate, with the appurtenances, estate, title and interest belonging to the said

here and assigns forever. It is covenanted that it is lawfully seized and possessed of said real estate in fee simple, have a good right to convey to, and that the same is unencumbered, except for 1981 City and County taxes which have been prorated and payment thereof assumed by Grantee. It further covenants and binds itself, its successors, assigns and representatives, to warrant and forever defend the title to said real estate to said E. WARNER BASS, TRUSTEE

(successors), heirs and assigns, against the lawful claims of all persons.

Witness its hand this 16th day of February 19 81 the corporate party, if any, having caused its name to be signed hereto by its duly authorized officers on said day and date.

Attest:

Third National Bank in Nashville, TN,
Executor and Trustee under the will
of Agnes Bennett, deceasedBy: Campbell Brown
Campbell Brown, Vice-President and
Real Estate Officer

February 24, 2015

BOOK 383 PAGE 637
2:49 pm

A tract of land lying wholly within the Ninth Civil District, partially within the City of Franklin, and bounded in general by MONSANTO on the North, by Wilson on the East, by Tennessee Highway 96 on the South, and by Curd Lane on the West, and being described according to the survey of C. K. McLeMore, Surveyor, dated December 7, 1977, as follows:

Beginning at an iron pin in the north margin of Tennessee Highway 96, at the southwest corner of Wilson; thence with said north margin the following six calls: 330.2 feet with a curve of radius 1597.1 feet to the right to a point; N 57° 06' W 116.1 feet to a point; N 32° 52' E 5.0 feet to a point; N 57° 06' W 263.3 feet to a concrete monument; N 34° 23' E 35.0 feet to a concrete monument; and 1239.8 feet with a curve to the left with radius 3899.72 feet to a concrete monument in the east margin of Curd Lane; thence with said east margin the two following calls: N 23° 30' W 90.0 feet to an iron pin and N 7° 30' E 310.0 feet to a point; thence N 82° 30' W 40.0 feet to a railroad spike in the center of Curd Lane; thence with said center line the two following calls: N 7° 30' E 390.0 feet to a railroad spike and N 8° 52' E 1441.9 feet to a railroad spike at Monsanto's southwest corner; thence with Monsanto's south line S 83° 39' E 1826.9 feet to an iron post in Wilson's west fence line; thence with his said west line S 7° 39' W 2994.8 feet to the point of beginning and containing 108.8 Acres, more or less, according to said survey.

Being part of the property conveyed to Agnes Bennett by deed from James B. Davis, Trustee, of record in Deed Book 58, page 36, Register's office for said county, and being part of the property devised to Third National Bank in Nashville, as Executor and Trustee under the will of Agnes Bennett, deceased, with full power to sell and convey without the joinder of any beneficiary, as of record in Will Book 40, page 686, County Court Clerk's Office for said County.

February 24, 2015

2:49 pm

BOOK 383 PAGE 638

STATE OF TENNESSEE
COUNTY OF DAVIDSONPersonally appeared before me, _____, a Notary Public in and
for said County and State, _____the within named bargainer, with whom I am personally acquainted, and who acknowledged that
executed the within instrument for the purposes therein contained.Witness my hand and official seal at _____ Tennessee
this _____ day of _____ 19____.

Commission expires _____ Notary Public

STATE OF TENNESSEE
COUNTY OF DAVIDSON

Before me, _____ the undersigned _____, a Notary Public of the State and
County aforesaid, personally appeared, Campbell, Brown
with whom I am personally acquainted, and who, upon oath, acknowledged him self to be Vice-President and
Real Estate Officer, Third National Bank in Nashville
the within named bargainer, a corporation, and that he as such Vice-President and Real Estate
being authorized so to do, executed the foregoing instrument for the purpose therein contained, by signing the same
of the corporation by himself as Vice-President and Real Estate Officer

Witness my hand and seal, at office in _____ Nashville, Tennessee
this _____ day of _____ February _____ 19____.

Commission expires _____ JAN. 20, 1986 _____ Notary Public



WILLIAMSON COUNTY — STATE OF TENNESSEE
Received for record the 19 day of Feb 15
at 1:10 o'clock A.M. Noted in Note Book 30 page 179
and Recorded in Book No. 383 page 636 State Tax
Paid 11.40 Fee 3.00 Recording Fee 4.00 Total 18.40
Receipt No. 23354 Witness my hand

_____ Register

WARRANTY DEED

FROM

TO

Compliments of

Colonial Title Company

2400 Crestmoor Road

NASHVILLE, TENNESSEE 37215

February 24, 2015**2:49 pm**

It appears that MTPC LLC's representative (Michael Sommi, Secretary) signing the Assignment and Assumption Agreement from the entity originally purchasing the land (Amence Development, LLC) has been appropriately authorized by each of the applicant LLC's 3 members to obligate the applicant to said agreement. Is there a resolution or similar document that reflects the LLC board or members' formal approval in this regard? Please briefly describe the process that applies to the agreement for the acquisition of the real estate.

Yes, a copy of the Written Consent of the Board of Directors of MTPC, LLC to Actions Taken Without a Meeting is submitted following this page.

February 24, 2015**2:49 pm**

**WRITTEN CONSENT
OF THE BOARD OF DIRECTORS
OF MTPC, LLC TO ACTIONS TAKEN WITHOUT A MEETING**

The undersigned being all of the members of the Board of Directors of MTPC, LLC, a Tennessee limited liability company (the "Company"), hereby unanimously authorize and adopt the following recitals and resolutions and consent to the following actions without a meeting pursuant to Section 7.13 of the Operating Agreement of the Company and Section 48-249-405 of the Tennessee Revised Limited Liability Company Act.

WHEREAS the Organizer of the Company appointed Terry Douglass as President, Mike Sommi as secretary and Chris Brown as Treasurer and Chief Financial Officer; and

WHEREAS the Board of Directors desires to ratify the appointment of officers by the Organizer; and

WHEREAS, the Company will apply for a Certificate of Need ("CON") to develop the Scott Hamilton Proton Center in Williamson County, and

WHEREAS it is necessary for the Company to enter a contract for the acquisition of property for the Scott Hamilton Proton Center pending the grant of a CON, and,

NOW, THEREFORE, IT IS HEREBY, RESOLVED, that Terry Douglass is elected as President, Mike Sommi as secretary and Chris Brown as Treasurer and Chief Financial Officer; and it is

FURTHER RESOLVED, that the Company is authorized to identify and select the appropriate parcel of land within Williamson County to construct the Scott Hamilton Proton Center, and it is

FURTHER RESOLVED, that the executive officers of the Company be, and they hereby are, authorized and directed to retain such consultants as are necessary to effectuate the intent of the foregoing resolutions; and it is

FURTHER RESOLVED, that the executive officers of the Company be, and they hereby are, authorized and directed to execute and deliver any and all documents necessary to effectuate the intent of the foregoing resolutions, the execution of such documents by such officers being a definitive determination of the necessity and appropriateness thereof, and further, that such officers are hereby authorized to do any and all such acts and deeds as they or legal counsel for the Company deem appropriate or necessary to effectuate the intent of these resolutions; and it is

FURTHER RESOLVED, that this instrument may be executed in multiple counterparts each of which shall have the full force and effect of an original and all of which together shall constitute one and the same document. This instrument may be transmitted by facsimile or

February 24, 2015**2:49 pm**


electronic mail in .pdf format. Signatures so transmitted shall bind the signing parties without regard to delivery or receipt of the original.

IN WITNESS WHEREOF, the undersigned, being all of the Members of the Board of Directors of the Company, have executed this Unanimous Written Consent of the Board of Directors To Actions Taken Without a Meeting effective as of January 7, 2015.

Directors:


Terry D. Douglass

Scott Hamilton


Mary Lou DuBois

February 24, 2015**2:49 pm**

WRITTEN CONSENT
OF THE BOARD OF DIRECTORS
OF MTPC, LLC TO ACTIONS TAKEN WITHOUT A MEETING

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FURTHER RESOLVED, that this instrument may be executed in multiple counterparts each of which shall have the full force and effect of an original and all of which together shall constitute one and the same document. This instrument may be transmitted by facsimile or electronic mail in .pdf format. Signatures so transmitted shall bind the signing parties without regard to delivery or receipt of the original.

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Directors:

Terry D. Douglass



Scott Hamilton

Mary Lou DuBois

February 24, 2015**2:49 pm**

It would be helpful to have some clarification of the various business entities that are involved in the acquisition of the property for the proposed facility. Please identify the member ownership and percentage of each member's ownership, and the business relationships between MTPC, LLC (inclusive of Provision Trust, Inc., and the 2 other current members) and Amence Development, LLC.

MTPC, LLC has entered an agreement with Amence Development, LLC, an unrelated real estate development company, to assist the applicant in identifying appropriate property, negotiating the purchase and assisting in the development.

MTPC, LLC has three tax-exempt, not-for-profit Members – Provision Trust, Inc. (48%), Scott Hamilton CARES Foundation, Inc. (26%) and Provision CARES Foundation, Inc. (26%). The cost of purchasing the property for the facility is expected to be financed with the proceeds of the bond issuance.

Regarding the purchase contract between the seller and Amence Development, LLC, please confirm the total purchase price of the 11.6 undeveloped acreage of the site, which is listed as \$7,326,792 in the notes on page 50 to the Project Costs Chart in the application. Please also confirm the purchase price amount that applies to the 1/22/15 Assignment and Assumption Agreement between the Amence Development, LLC and the applicant LLC.

The total purchase price for the entire 11.6 acre parcel is \$7,326,792. The assignment to MTPC, LLC is for the entire property for the full purchase price.

February 24, 2015**2:49 pm**

Review of the Closing Date provisions in the 1/16/15 purchase agreement revealed a maximum period of not more than 210 days or 7 months ending on or about August 17, 2015 for formal conveyance of the property. If the closing date is delayed to August 2015, it appears that the applicant LLC will not have control of the site on the date of the HSDA Board's hearing of the application on or about May 27, 2015. Please explain what measures might be taken to minimize extensions to the closing date on the property.

Since the permitted extensions under the Purchase Agreement extend the contract through August, 2015, the applicant LLC will have contractual control of the site through the end of May 27th hearing date and will be able to promptly close upon receipt of the Certificate of Need. The applicant is presently undertaking its due diligence with the intent of completing the same within ninety (90) days to ensure that upon the grant of the CON, the applicant will be in a position to promptly proceed to closing.

4. Section A, Applicant Profile, Item 13

The response is noted. Given Provision Trust, Inc.'s controlling membership interest in the applicant LLC and "lessons learned" from its operation of the Provision Center for Proton Therapy in Knoxville approved in CN1001-010A, please provide an update regarding coverage of proton therapy services under Medicare, TennCare, and other state's Medicaid programs within the applicant's proposed service area.

The Medicare Administrative Contractor (MAC) for Tennessee, Cahaba Government Benefit Administrators, LLC (Cahaba) released their Local Coverage Determination (LCD) policy for proton therapy on July 1, 2013. The LCD provides broad coverage for proton therapy for the majority of cancer indications. TennCare MCOs are currently providing coverage for proton therapy on a case-by-case basis. We are in continued discussions with all TennCare MCOs, Alabama Medicaid, and are continuing to explore opportunities with other state Medicaid programs.

Please also describe coverage that is available for proton therapy services through the major commercial health insurance companies in the applicant's proposed service area. What is their typical reimbursement for these services?

Major commercial health insurance companies in Tennessee also provide coverage for proton therapy for cancer indications but the scope varies by insurer and is more limited than Medicare. Examples include Aetna, Blue Cross/Blue Shield of Tennessee, Cigna, Humana, and United Healthcare. The average reimbursement per treatment by commercial health insurance companies for proton therapy received by the Provision Center for Proton Therapy in Knoxville during its first year of operation was \$2,003.97.

5. Section B, Project Description, Item II A.

As the applicant has noted, many of the current proton therapy centers appear to be affiliated with nationally renowned teaching hospitals. Is the applicant able to document interest of same through the Scott Hamilton CARES Foundation or the Provision Cares Foundation, Inc.? Please include a brief description explaining how the applicant will be able to benefit from potential affiliations with health care organization(s) such as the Monroe Carell Children's Hospital, Vanderbilt Ingram Cancer Center or Sarah Cannon Cancer Center organizations that have established and valued referral relationships throughout the proposed service area.

Similar to the policy of the Provision Center for Proton Therapy in Knoxville, renowned oncology centers in the Primary Service Area committed to oncology research and treatment will be invited and encouraged to participate in the project, both through clinical partnerships and through opportunities for membership in the ownership LLC. Benefits from potential affiliations are significant and can result in advances in clinical research, treatments, and improved outcomes for cancer patients throughout Middle Tennessee and the Central Southeastern United States.

These relationships take time to develop. Detailed discussions prior to receipt of a Certificate of Need would not be productive. The long implementation schedule for a project such as this will afford ample time for the applicant to pursue relationships with leading organizations in oncology research and cancer care. It is the applicant's intention to do so.

In terms of existing resources, it would be helpful to have a better understanding of how the applicant will utilize existing radiation therapy and diagnostic imaging services available in the service area as opposed to potentially duplicating same. Please discuss the applicant's intentions in this regard.

There is no duplicative imaging or radiation therapy technology proposed in this application. Proton therapy is a new option for treatment of cancer in the Primary Service Area. Referring physicians and their patients will make all decisions as to which services to utilize. It is expected that patients at the Scott Hamilton Proton Center who need any resource other than the proton beam technology in this project would be referred by physicians to existing resources close to the project, or in their county of origin.

In terms of medical direction of the proposed center, review of Section 3.2 of the proposed management agreement between MTPC, LLC (applicant LLC) and Provision Proton Centers, LLC revealed that MTPC shall be responsible for appointing a medical director of the center. As such, please briefly discuss the arrangements that may be provided in this regard. Please also describe the process to be followed by the governing body of the applicant LLC to select and approve the most qualified candidate for the medical director position.

MTPC executive leadership will follow the same protocol adopted by the Provision Center for Proton Therapy for recruiting a Medical Director of the center. A national search will be conducted to identify an experienced radiation oncologist appropriately trained in proton therapy who can provide medical leadership of the clinical program. Promising candidates will be personally interviewed by a search committee representing the applicant and

its affiliated entities. The committee will recommend one or more candidates to the applicant's Board and the Board will choose the Medical Director.

6. Section B, Project Description, Item II C.

The description of proton therapy as the advanced form of radiation treatment available is noted. What excerpts can be provided from any of the studies included in the medical literature on page 21 (or other related sources) that justifies the higher cost of proton therapy over traditional radiation therapy by improved medical outcomes and/or reduced side effects? Please clarify.

In the application the following excerpts were provided from the referenced recent studies demonstrating the significant clinical benefits proton therapy provides over traditional radiation therapy. Six of the seven excerpts provided direct clinical benefit comparisons to traditional radiation therapy. We have outlined in bold the specific comparison in the excerpts below. Because of the ability to hypofractionate (provide fewer, larger doses) treatment for many indications with proton therapy, the cost of treatment is actually equal to or less than traditional radiation therapy. The applicant is not aware of any clinical research comparisons to CyberKnife technology.

- Proton beam radiation therapy for partial breast radiation produced excellent ipsilateral breast recurrence-free survival with minimal toxicity. **Cosmetic results may be improved over those reported with photon-based techniques** due to reduced breast tissue exposure with proton beam.¹

¹ Bush, David A., Sharon Do, Sharon Lum, Carlos Garberoglio, et al. 2014. "Partial Breast Radiation Therapy With Proton Beam: 5-Year Results With Cosmetic Outcomes." *International Journal of Radiation Oncology*Biophysics* 90 (3): 501–5. doi:10.1016/j.ijrobp.2014.05.1308.

- A Mayo Clinic meta-analysis of 41 sinus and nasal cavity cancer observational studies noted better loco-regional control, disease-free survival, and overall survival in all patients who were treated with charged particle therapy (protons), compared with those receiving photon therapy, at either 5 years or at longest duration of treatment, or both periods.²
- Gastrostomy tubes (abdominal feeding tubes) decrease by over 50% with proton therapy in comparison to conventional radiation therapy during the treatment of oropharyngeal cancer patients.³
- Higher doses of proton radiation can be delivered to lung tumors with a lower risk of esophagitis and pneumonitis in comparison to conventional radiation therapy.⁴
- Proton Therapy can reduce the calculated incidence of radiogenic second cancers in prostate patients compared with IMRT. The finding was principally attributed to the ability of proton therapy to reduce the primary dose in sensitive organs near the target volume compared with IMRT.⁵

² Patel, Samir H, Zhen Wang, William W Wong, Mohammad Hassan Murad, et al. 2014. "Charged Particle Therapy versus Photon Therapy for Paranasal Sinus and Nasal Cavity Malignant Diseases: A Systematic Review and Meta-Analysis." *The Lancet Oncology*, June. doi:10.1016/S1470-2045(14)70268-2.

³ Patel, Samir H, Zhen Wang, William W Wong, Mohammad Hassan Murad, Courtney R Buckey, Khaled Mohammed, Fares Alahdab, et al. 2014. "Charged Particle Therapy versus Photon Therapy for Paranasal Sinus and Nasal Cavity Malignant Diseases: A Systematic Review and Meta-Analysis." *The Lancet Oncology*, June. doi:10.1016/S1470-2045(14)70268-2.

⁴ Patel, Samir H, Zhen Wang, William W Wong, Mohammad Hassan Murad, Courtney R Buckey, Khaled Mohammed, Fares Alahdab, et al. 2014. "Charged Particle Therapy versus Photon Therapy for Paranasal Sinus and Nasal Cavity Malignant Diseases: A Systematic Review and Meta-Analysis." *The Lancet Oncology*, June. doi:10.1016/S1470-2045(14)70268-2.

⁵ Fontenot, Jonas D., Andrew K. Lee, et al. 2009. "Risk of Secondary Malignant Neoplasms From Proton Therapy and Intensity-Modulated X-Ray Therapy for Early-Stage Prostate Cancer." *International Journal of Radiation Oncology • Biology • Physics* 74 (2): 616–22. doi:10.1016/j.ijrobp.2009.01.001.

- The use of proton therapy was not associated with a significantly increased risk of secondary malignancies compared with photon therapy.⁶

What plans if any, does the applicant have to collaborate with existing linear accelerator radiation therapy service providers in the service area such that care coordination or continuity of care for patients of the center is available?

The SHPC facility will be immediately adjacent to the linear accelerator that is available at Vanderbilt-Ingram Cancer Center's facility in Williamson County. The applicant intends to work with that immediately adjacent provider on arrangements for the complete technical and clinical integration of the linear accelerator with the SHPC facility. This is consistent with the set-up at the Provision Center for Proton Therapy facility located in Knoxville, which also relies on the conventional radiation therapy resource at the immediately adjacent Provision Radiation Therapy facility. Provided that the same arrangements can be made in Williamson County, the applicant expects to use the existing linear accelerator for purposes of providing combination treatment and potential down-time coverage. In the absence of the complete technical and clinical integration with an on-site or immediately adjacent linear accelerator, the applicant will not offer combination therapy.

⁶ Chung, Christine S, Torunn I Yock, Kerrie Nelson, Yang Xu, et al. 2013. "Incidence of Second Malignancies among Patients Treated with Proton versus Photon Radiation." *International Journal of Radiation Oncology, Biology, Physics* 87 (1): 46–52. doi:10.1016/j.ijrobp.2013.04.030.

7. Section B, Project Description, Item ILE.

Item 1.a.1 (cost) - The total equipment cost is the same as reflected in both the table on page 33 and the Project Costs Chart on page 52. However, the amount in the vendor quote appears to be provided in Japanese Yen equivalents (JP¥ 5,490,000,000) and excludes costs for a treatment planning system, an oncology information system, shipping and taxes. Please clarify by documenting that the amounts in the vendor quote support what is identified in the Project Cost Chart cost for the unit. As a suggestion, it would be helpful to provide written documentation from the vendor to clarify, such as an addendum to the quote provided with the application.

The equipment quote provided by the vendor included only the major medical equipment in this project – the proton therapy equipment. The proton therapy equipment vendor does not provide treatment planning systems or oncology information systems. Those are purchased separately. Formal quotes were not obtained for such ancillary equipment because those items are not themselves considered major medical equipment. Their cost was estimated based on

- (a) the recent experience of purchasing such equipment at the Provision Center for Proton Therapy, and
- (b) informal discussions with the manufacturers of this equipment.

Please see the Proton Therapy Equipment Chart in Section B.II.E of the application, which provided the costs of all equipment in the project. The totals are consistent with the Project Cost Chart.

Item 1.a.3 - Please identify the primary clinical applications that apply to the service with brief description of a typical course of treatment, as appropriate. In your discussion, please summarize how the course of treatment compares between a proton therapy service and a linear accelerator service.

The primary clinical applications that apply to proton therapy are the majority of the same indications that apply to traditional radiation therapy.

That being said due to limited access and capacity of proton therapy throughout the country the major indications treated by proton therapy facilities thus far have been prostate, head & neck, central nervous system, lung, breast and pediatric cancers.

The unique physical characteristics of protons allow for the treatment of certain cancers (Prostate, Breast, Lung, Liver and others) with substantially fewer proton therapy treatments than traditional radiation therapy. This delivery method known as hypofractionation, substantially reduces the course of treatment and the time patients spend receiving treatment.

Otherwise, the course of treatment is similar to that of traditional radiation therapy, with the exception that the actual proton treatments can take slightly longer than traditional radiation therapy treatments, due to

- (a) increased imaging required to enable precision targeting of proton beams, and
- (b) the need to share the proton beam among several treatment rooms.

8. Section B, Project Description, Item IV (Floor Plan)

One of the 3 shielded patient treatment areas stations shown on the 1st Floor Plan is labeled Horizontal Beam Treatment Room while the other 2 are shown as Gantry Treatment Areas. The description provided on page 9 for Design and Space requirements mentions a fixed beam treatment room and 2 gantry rooms. Is the horizontal room the same as the fixed beam room? Please clarify.

The horizontal beam and the fixed beam are synonymous and the terms are used interchangeably throughout the industry. The proton beam in this treatment room is fixed in a horizontal plane and does not have the capability to rotate 360 degrees around the patient like the gantries.

9. Section C, Need, Item 1

It appears that responses to the 5 Principles in the State Health Plan were omitted from the application. Please include your response for this item.

1. Healthy Lives

The purpose of the State Health Plan is to improve the health of Tennesseans.

Every person's health is the result of the interaction of individual behaviors, society, the environment, economic factors, and our genetic endowment. The State Health Plan serves to facilitate the collaboration of organizations and their ideas to help address health at these many levels.

Tennessee ranks 22nd in cancer incidence and ranks 5th in cancer death rate in the United States. The Scott Hamilton Proton Center will help address this unfortunate statistic by bringing one of the most advanced cancer treatment technologies to the Middle Tennessee region and to the state. Ground-breaking clinical research with this new technology will ultimately help to save the lives of more Tennesseans.

2. Access to Care

Every citizen should have reasonable access to health care.

Many elements impact one's access to health care, including existing health status, employment, income, geography, and culture. The State Health Plan can provide standards for reasonable access, offer policy direction to improve access, and serve a coordinating role to expand health care access.

The Scott Hamilton Proton Center (SHPC) will provide Middle Tennesseans with reasonable physical access to one of the most advanced cancer treatment technologies – one which is not currently available in this region. As a not-for-profit center, a critical component of the applicant's mission is to provide cancer care to cancer patients regardless of existing health status, employment, income, geography, or culture. SHPC's charity care policy will allow for poor and underserved patients to have access to this state-of-the-art treatment.

3. Economic Efficiencies

The state's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies and the continued development of the state's health care system. The State Health Plan should work to identify opportunities to improve the efficiency of the state's health care system and to encourage innovation and competition.

One of the goals of the Scott Hamilton Proton Center is to further clinical research in order to further define and evaluate the potential of proton therapy to treat a greater number of cancer indications at a reduced cost. The project poses no competitive threat to the existing marketplace, as proton therapy is currently not available or proposed in the Middle Tennessee region. The project is a significant innovation for the region.

4. Quality of Care

Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers. Health care providers are held to certain professional standards by the state's licensure system. Many health care stakeholders are working to improve their quality of care through adoption of best practices and data-driven evaluation.

The Scott Hamilton Proton Center plans to provide high quality cancer care demonstrated by the commitment to seek licensure and certified registration by the Tennessee Department of Environment & Conservation's Department of Radiological Health. In addition, the center will seek membership in the National Cancer Institute's National Clinical Trial Network and accreditation from the Imaging & Radiation Oncology Core program and the American College of Radiation Oncology to assure high quality delivery of care to cancer patients in the Middle Tennessee area.

5. Health Care Workforce

The state should support the development, recruitment, and retention of a sufficient and quality health care workforce. The state should consider developing a comprehensive approach to ensure the existence of a sufficient, qualified health care workforce, taking into account issues regarding the number of providers at all levels and in all specialty and focus areas, the number of professionals in teaching positions, the capacity of medical, nursing, allied health and other educational institutions, state and federal laws and regulations impacting capacity programs, and funding.

Providing highly skilled health care workers at the Scott Hamilton Proton Center is a top priority. Proton Therapy requires a uniquely specialized work force that is limited in nature. To address this unique need SHPC will search locally and nationwide to identify the best candidates for these positions. Additionally, for positions where experienced staff cannot be identified SHPC will utilize the new Provision Proton Therapy Training Center recently made available on the Dowell Springs campus in Knoxville to train new staff.

Given the plans for construction of a new 36,083 square foot building for the outpatient proton therapy center at an estimated cost of approximately \$17,306,081, please also provide responses for the criteria pertaining to Construction and Renovation criteria in this section.

This is criteria is not applicable to this project because the project does not include an existing facility.

February 24, 2015**2:49 pm**

With respect to the responses provided for Megavoltage Radiation Therapy Service, please address the following:

Item 4 - It is understood that this criterion may not apply to the proposed proton therapy service. However, the response should also recognize the utilization of existing radiation therapy linear accelerator units in the 38 county TN service area. Please provide the utilization by provider for CY 2013 by contacting Alecia Craighead, HSDA Statistical Analyst III, for assistance in obtaining the data from the HSDA Equipment Registry.

This data is provided in the chart for the response to question 11.

Important Note: revised criteria for this standard has been developed and implemented by HSDA and TDH as part of the State Health Plan process. Please see Exhibit 1 at the end of this questionnaire for the template that applies to this standard.

Standards and Criteria**1. Utilization Standards for MRT Units.****a. Linear Accelerators not dedicated to performing SRT and/or SBRT procedures:**

- i. Full capacity of a Linear Accelerator MRT Unit is 8,736 procedures, developed from the following formula: 3.5 treatments per hour, times 48 hours (6 days of operation, 8 hours per day, or 5 days of operation, 9.6 hours per day), times 52 weeks.
- ii. Linear Accelerator Minimum Capacity: 6,000 procedures per Linear Accelerator MRT Unit annually, except as otherwise noted herein.
- iii. Linear Accelerator Optimal Capacity: 7,688 procedures per Linear Accelerator MRT Unit annually, based on a 12% average downtime per MRT unit during normal business hours annually.
- iv. An applicant proposing a new Linear Accelerator should project a minimum of at least 6000 MRT procedures in the first year of service in its Service Area, building to a minimum of 7,688 procedures per year by the third year of service and for every year thereafter.

This criterion is not applicable to a Proton Beam Therapy Unit.

b. For Linear Accelerators dedicated to performing only SRT procedures, full capacity is 500 annual procedures.

This criterion is not applicable to a Proton Beam Therapy Unit.

c. For Linear Accelerators dedicated to performing only SRT/SBRT procedures, full capacity is 850 annual procedures.

This criterion is not applicable to a Proton Beam Therapy Unit.

- d. An exception to the standard number of procedures may occur as new or improved technology and equipment or new diagnostic applications for Linear Accelerators develop. An applicant must demonstrate that the proposed Linear Accelerator offers a unique and necessary technology for the provision of health care services in the proposed Service Area.

This criterion is not applicable to a Proton Beam Therapy Unit.

- e. Proton Beam MRT Units. As of the date of the approval and adoption of these Standards and Criteria, insufficient data are available to enable detailed utilization standards to be developed for Proton Beam MRT Units.

No response required.

2. Need Standards for MRT Units.

- a. For Linear Accelerators not dedicated solely to performing SRT and/or SBRT procedures, need for a new Linear Accelerator in a proposed Service Area shall be demonstrated if the average annual number of Linear Accelerator procedures performed by existing Linear Accelerators in the proposed Service Area exceeds 6,000.

This criterion is not applicable to a Proton Beam Therapy Unit.

- b. For Linear Accelerators dedicated to performing only SRT procedures, need in a proposed Service Area shall be demonstrated if the average annual number of MRT procedures performed by existing Linear Accelerators dedicated to performing only SRT procedures in a proposed Service Area exceeds 300, based on a full capacity of 500 annual procedures.

This criterion is not applicable to a Proton Beam Therapy Unit.

- c. For Linear Accelerators dedicated to performing only SRT/SBRT procedures, need in a proposed Service Area shall be demonstrated if the average annual number of MRT procedures performed by existing Linear Accelerators dedicated to performing only SRT/SBRT procedures in a proposed Service Area exceeds 510, based on a full capacity of 850 annual procedures.

This criterion is not applicable to a Proton Beam Therapy Unit.

- d. Need for a new Proton Beam MRT Unit: Due to the high cost and extensive service areas that are anticipated to be required for these MRT Units, an applicant proposing a new Proton Beam MRT Unit shall provide information regarding the utilization and service areas of existing or planned Proton Beam MRT Units' utilization and service areas (including those that have received a CON), if they provide MRT services in the proposed Service Area and if that data are available, and the impact its application, if granted, would have on those other Proton Beam MRT Units.

There is one Proton Beam MRT Unit CON operational in Tennessee at the Provision Center for Proton Therapy in Knoxville. This center began operations in January 2014 and utilization for the year was 8,846 treatments. The Primary Service Area of this unit covers 36 Tennessee counties in the eastern third of the state from the Sequatchie Valley, Crossville, and Pickett County areas eastward. Outside Tennessee, the Primary Service Area covers 38 counties in Northern Georgia, Western North Carolina, the Southwestern corner of Virginia, and Southeastern Kentucky. None of those counties or parts of adjoining States overlaps with the primary service area of this project in Middle Tennessee. Therefore, the applicant does not expect the Scott Hamilton Proton Center in Middle Tennessee to have any adverse competitive impact on the Provision facility in East Tennessee.

A second Proton Beam MRT Unit CON in Tennessee has been granted CON approval but has not yet implemented. St. Jude Children's Research Hospital plans to begin proton beam treatments in 2017 and projects a utilization of 2,944 treatments in its first year. The Primary Service Area for this planned facility is unique in the fact that St. Jude is a nationally recognized provider exclusively serving pediatric cancer patients. Accordingly, its Primary Service Area will consist of the States of Tennessee, Mississippi, Louisiana, Arkansas, Alabama, Illinois, Missouri, Florida, and Texas; and its patients will all be pediatric patients. The applicant, however, will serve mostly adult patients, and will have a more tightly focused Primary Service Area. The applicant does not expect the Scott Hamilton Proton Center to adversely impact the St. Jude program in any way.

- e. **An exception to the need standards may occur as new or improved technology and equipment or new diagnostic applications for MRT Units develop. An applicant must demonstrate that the proposed MRT Unit offers a unique and necessary technology for the provision of health care services in the proposed Service Area.**

This criterion is not applicable to a Proton Beam Therapy Unit.

3. Access to MRT Units.

- a. **An MRT unit should be located at a site that allows reasonable access for residents of the proposed Service Area.**

The project site is on the east side of Carothers Parkway within a few minutes' drive of Exit 65 (Highway 96) on I-65 in Franklin, TN. This location is central to the region the project will serve. Good Federal and State highways connect Franklin to all parts of the primary service area. The Exhibit One map and county listing in section B of the application show that all 38 counties in the primary service area are within a 2- hour drive of the project site. The drive time data was obtained from Google Maps. The project site is conveniently located within thirty minutes' drive of Nashville's international airport and of the location where three major interstates (I-40, I-24 and I-65) meet. Location maps are provided in Attachment C, Need-3.

- b. **An applicant for any proposed new Linear Accelerator should document that the proposed location of the Linear Accelerator is within a 45-minute drive time of the majority of the proposed Service Area's population.**

This criterion is not applicable to a Proton Beam Therapy Unit.

- c. Applications that include non-Tennessee counties in their proposed Service Areas should provide evidence of the number of existing MRT units that service the non-Tennessee counties and the impact on MRT unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity (if that data are available).

This project includes non-Tennessee counties only in its Secondary Service Area. There are currently no Proton Beam Therapy Units in the Secondary Service Area with the exception of the unimplemented Unit at St. Jude Children's Research Hospital in Memphis, which is limited to pediatric cancer patients. St Jude has projected performing 2,944 treatments in Year One and 4,577 treatments in Year Three. Due to the 9-state Primary Service Area of the St. Jude Proton Beam Therapy Unit, the projected impact of this project on St Jude's utilization, and vice versa, are negligible.

- 4. Economic Efficiencies. All applicants for any proposed new MRT Unit should document that lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

This criterion is not applicable to a Proton Beam Therapy Unit.

February 24, 2015**2:49 pm**

5. Separate Inventories for Linear Accelerators and for other MRT Units. A separate inventory shall be maintained by the HSDA for Linear Accelerators, for Proton Beam Therapy MRT Units, and, if data are available, for Linear Accelerators dedicated to SRT and/or SBRT procedures and other types of MRT Units.

No response required.

6. Patient Safety and Quality of Care. The applicant shall provide evidence that any proposed MRT Unit is safe and effective for its proposed use.

- a. The United States Food and Drug Administration (FDA) must certify the proposed MRT Unit for clinical use.

FDA clearance letter provided in Attachment B.II.E.1.

- b. The applicant should demonstrate that the proposed MRT Units shall be housed in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.

The proposed Proton Beam Therapy Unit in this project will be housed in a concrete shielded vault designed by a medical physicist appropriately trained in radiation shielding design. The shielding design will be submitted to the Tennessee Department of Environment and Conservation's Department of Radiological Health for their review and approval. The architect's cost attestation letter provides assurance of conformity to applicable standards and requirements.

- c. The applicant should demonstrate how emergencies within the MRT Unit facility will be managed in conformity with accepted medical practice. Tennessee Open Meetings Act and/or Tennessee Open Records Act.**

Emergencies within the Proton Beam Therapy facility will be managed according to policies developed for the facility by the Medical Director and executive leadership. All emergencies or incidents that are required to be reported by regulatory agencies will be reported in adherence to the Tennessee Open Meetings Act and/or the Tennessee Open Records Act.

- d. The applicant should establish protocols that assure that all MRT Procedures performed are medically necessary and will not unnecessarily duplicate other services.**

The Medical Director of the Scott Hamilton Proton Center will establish protocols and procedures that provide assurance that all medical procedures will be medically necessary, and will not unnecessarily duplicate other medical services.

- e. An applicant proposing to acquire any MRT Unit shall demonstrate that it meets the staffing and quality assurance requirements of the American Society of Therapeutic Radiation and Oncology (ASTRO), the American College of Radiology (ACR), the American College of Radiation Oncology (ACRO) or a similar accrediting authority such as the National Cancer Institute (CNI). Additionally, all applicants shall commit to obtain accreditation from ASTRO, ACR or a comparable accreditation authority for MRT Services within two years following initiation of the operation of the proposed MRT Unit.**

The Scott Hamilton Proton Center will seek to meet all staffing and quality assurance requirements of the American College of Radiation Oncology. This will be accomplished by seeking accreditation of the facility through said organization.

- f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.**

The applicant anticipates having a contractual relationship with the Williamson Medical Center or other local providers for imaging support and other services. Emergency transfer agreements will also be proposed to Williamson Medical Center and to hospitals in Davidson County with the Scott Hamilton Proton Center Medical Director an active member of the agreement.

- g. All applicants should provide evidence of any onsite simulation and treatment planning services to support the volumes they project and any impact such services may have on volumes and treatment times.**

On-site simulation and treatment planning services are planned as part of the facility and included in the projected Equipment Chart in Section B.II.E of the application. The availability of this equipment allows for better efficiencies of providing treatments reducing the time required to prepare a patient's treatment plan if they were not available.

7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.

The Scott Hamilton Proton Center will submit all required data by the dates outlined by the HSDA Equipment Registry.

8. In light of Rule 0720-11.01, which lists the factors concerning need on which an application may be evaluated, and Principle No. 2 in the State Health Plan, "Every citizen should have reasonable access to health care," the HSDA may decide to give special consideration to an applicant:

- a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;
- b. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program; or
- c. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

No response required.

February 24, 2015**2:49 pm****10. Section C, Need, Item 4 (Service Area)**

In terms of special needs, it would be helpful to have an appreciation of radiation therapy utilization by residents of the TN portion of the service area with comparison to the statewide average for TN. Please complete the table below using information from the HSDA Equipment Registry. Please contact Alecia Craighead, Stat III for assistance.

The requested table is submitted on the following page.

February 24, 2015**2:49 pm**

Radiation Therapy Utilization by Residents of 38 - County TN Service Area					
PSA County	2011 Procedures	2012 Procedures	2013 Procedures	% Change '11-'13	2013 Use Rate per 1,000 Population
Bedford	1848	1829	1812	-1.9%	38.80
Cannon	598	646	662	10.7%	47.24
Cheatham	2211	1709	2217	0.3%	55.98
Clay	354	415	393	11.0%	50.91
Coffee	1362	1520	3470	154.8%	64.52
Davidson	30472	29166	29920	-1.8%	46.07
DeKalb	990	255	836	-15.6%	44.19
Dickson	2603	2953	2885	10.8%	57.02
Franklin	916	603	1656	80.8%	40.29
Giles	1564	1993	1918	22.6%	65.40
Grundy	408	255	693	69.9%	51.73
Hickman	1803	1448	1424	-21.0%	58.38
Houston	730	487	559	-23.4%	66.88
Humphreys	1250	1418	1228	-1.8%	66.42
Jackson	1048	335	857	-18.2%	75.47
Lawrence	2758	2348	3093	12.1%	73.16
Lewis	963	858	1129	17.2%	93.22
Lincoln	759	652	1216	60.2%	35.79
Macon	812	938	658	-19.0%	28.66
Marshall	2249	1799	2032	-9.6%	65.21
Mauzy	5940	5348	5881	-1.0%	71.69
Montgomery	6057	6239	5679	-6.2%	30.85
Moore	30	69	89	196.7%	13.97
Overton	1515	1658	1137	-25.0%	50.81
Perry	461	540	452	-2.0%	56.71
Putnam	5218	4953	6002	15.0%	79.34
Robertson	3093	3299	3328	7.6%	48.00
Rutherford	9429	9904	9410	-0.2%	33.00
Smith	480	705	1040	116.7%	53.48
Stewart	933	687	634	-32.0%	47.19
Sumner	6576	6843	6773	3.0%	39.98
Trousdale	106	135	93	-12.3%	11.56
Van Buren	147	380	348	136.7%	63.78
Warren	1939	1552	2013	3.8%	49.95
Wayne	719	586	1016	41.3%	60.16
White	2168	1884	2185	0.8%	82.11
Williamson	7375	8492	8115	10.0%	40.98
Wilson	3867	3131	4421	14.3%	36.35
Statewide	111751	108032	117274	4.9%	46.50

*Medical Equipment Registry 2/20/2015 & Tennessee Department of Health/Health Statistics
(population)*

11. Section C, Need, Item 5

The status of other CON approved proton therapy centers in Tennessee is noted. It appears that utilization of the Knoxville facility is expected to increase from 8,846 treatments in 2014 to 22,785 treatments in 2015. Please explain the factors driving such a large anticipated increase in patient volumes.

Year One utilization will be limited not by referral demand, but rather by available capacity. During Year One, the manufacturer and the facility's medical physics team must accept and commission each Proton Beam Therapy Unit treatment room individually, in sequential order over a 9-month period. Due to this ramp-up schedule the capacity of the facility will be limited in most of Year One. But in Year Two, all three treatment rooms will be available expanding the capacity of the facility allowing more patients to be accepted and treated.

With respect to existing radiation therapy service providers in the proposed 38 county Tennessee portion of the service area, please complete the table below using data from the HSDA Equipment Registry. Please feel free to contact Alecia Craighead, Stat III for assistance with this request.

The requested table is submitted on the following page.

February 24, 2015**2:49 pm**

38 - County TN Service Area Historical Utilization						
Provider	# of Units	2011 Procedures	2012 Procedures	2013 Procedures	% Change '11-'13	Use by Residents of TN Service Area - CY2013
Community Cancer Center of Tullahoma	2	4491	5273	3652	-23.0%	98.8%
St. Thomas Midtown Hospital	2	6193	6514	6493	4.6%	99.0%
St. Thomas West Hospital	2	7140	6450	6996	-2.1%	94.3%
TriStar Centennial Medical Center	2	7894	6664	7751	-1.8%	97.3%
TriStar Skyline Medical Center	1	5722	5446	5745	0.4%	98.3%
TriStar Summit Medical Center - ODC	1	5012	4884	5275	5.0%	99.7%
Vanderbilt University Hospital	4	31143	31942	30492	-2.1%	86.6%
Natchez Imaging Center	1	3919	4268	4090	4.2%	99.8%
Maury Regional Medical Center	2	12556	11604	13354	6.0%	98.9%
Vanderbilt Maury Radiation Oncology*	1	0	0	557	100.0%	99.3%
Gateway Vanderbilt Cancer Treatment Center	1	6800	6949	6936	2.0%	85.2%
Cookeville Regional Medical Center	2	12707	11772	12876	1.3%	97.7%
St. Thomas Rutherford Hospital	2	9689	10511	10767	10.0%	100.0%
TriStar Stonecrest Medical Center	1	2049	2072	2186	6.3%	99.3%
Sumner Regional Medical Center	1	4038	4043	3979	-1.5%	98.4%
Vanderbilt Ingram Cancer Center at Franklin	1	5753	5975	5503	-4.5%	100.0%
University Medical Center**	1	2648	2561	1878	-41.0%	43.0%
TOTAL	27	127754	126928	128530	0.6%	94.1%

* Opened in late 2013

**Cancer Care Center at University Medical Center utilization is reported under the hospital since ownership of the linear accelerator transferred to the hospital in 2012.

Medical Equipment Registry - 2/20/2015

12. Section C, Need, Item 6 (Applicant's Projected Utilization)

Based on projected utilization for CY2020, it appears that the each patient would receive an average of approximately 30 treatments at roughly 26 total hours per year during his/her course of treatment. Please describe the factors that apply to this estimate such as the type of cancer, the size of the tumor and/or the degree of metastasis? In your response, please describe how the course of treatment estimate compares with rates of other similar providers in TN and other states.

The factors that determined this information are provided in EXHIBIT FIVE - C of the application. The number of minutes required for treatment of each indication is based upon the complexity of the setup, the amount of imaging required and the number of fields required to deliver the daily treatment dose. Currently it is rare for proton therapy to be used for patients with distant metastasis unless the area has been previously treated with traditional radiation therapy. These estimates compare favorably with the Provision Center for Proton Therapy in Knoxville and were based on its experience in 2014. We do not have access to this information from other proton therapy facilities.

It appears that the Thomson Healthcare cancer incidence data is based on the application of national use rates to the service area population. Since cancer incidence data for the Tennessee counties is available from the Tennessee Cancer Registry please identify and compare this data to your model for the Tennessee portion of your service area.

The requested information is submitted on the following page.

February 24, 2015**2:49 pm**

Cancer Incidence Data Comparison Chart				
County in Primary Service Area	State	Tennessee Cancer Registry Data 2006-2010* Annualized	Truven Data 2014 Cases	% Difference
Bedford County	TN	213	271	21.4%
Cannon County	TN	77	81	4.9%
Cheatham County	TN	200	201	0.5%
Clay County	TN	49	40	-22.5%
Coffee County	TN	300	380	21.1%
Davidson County	TN	2,817	2,978	5.4%
DeKalb County	TN	100	128	21.9%
Dickson County	TN	262	282	7.1%
Franklin County	TN	254	264	3.8%
Giles County	TN	170	211	19.4%
Grundy County	TN	82	94	12.8%
Hickman County	TN	139	141	1.4%
Houston County	TN	48	64	25.0%
Humphreys County	TN	118	128	7.8%
Jackson County	TN	71	70	-1.4%
Lawrence County	TN	222	311	28.6%
Lewis County	TN	73	66	-10.6%
Lincoln County	TN	186	247	24.7%
Macon County	TN	129	121	-6.6%
Marshall County	TN	166	185	10.3%
Maury County	TN	405	412	1.7%
Montgomery County	TN	571	861	33.7%
Moore County	TN	30	25	-20.0%
Overton County	TN	132	135	2.2%
Perry County	TN	53	58	8.6%
Putnam County	TN	367	529	30.6%
Robertson County	TN	322	357	9.8%
Rutherford County	TN	908	1,253	27.5%
Smith County	TN	101	108	6.5%
Stewart County	TN	82	102	19.6%
Sumner County	TN	806	933	13.6%
Trousdale County	TN	42	40	-5.0%
Van Buren County	TN	29	27	-7.4%
Warren County	TN	218	267	18.4%
Wayne County	TN	95	124	23.4%
White County	TN	156	204	23.5%
Williamson County	TN	739	1,118	33.9%
Wilson County	TN	540	608	11.2%
TOTAL		11,272	13,425	16.0%

*Tennessee Department of Health Division of Policy, Planning & Assessment - Cancer in Tennessee 2006-2010, Appendix IV. Cancer Incidence & Mortality, All Sites Combined, Age-adjusted, By Resident County, Tennessee, 2006-2010

February 24, 2015**2:49 pm**

It should be noted that data pertaining to actual radiation therapy treatment utilization is available from the HSDA Equipment Registry. Given the 15%-20% rate assumption (%of radiation therapy treatments eligible for proton therapy) identified in your step-down methodology on page 45, how might this compare to the projected utilization of the proposed proton therapy unit when taking into account radiation therapy utilization in the 38-county Tennessee PSA from the HSDA Equipment Registry for 2011 - 2013? Please provide a brief comparison in this regard.

The requested information is submitted on the following page

February 24, 2015**2:49 pm**

38-COUNTY RADIATION THERAPY UTILIZATION STEP-DOWN COMPARISON				
STEP	PROJECTIONS	CY2011	CY2012	CY2013
3	PROCEDURES APPROPRIATE FOR RADIATION THERAPY	127,754	126,928	128,530
4	PERCENT APPROPRIATE FOR REFERRAL TO PROTON THERAPY	15-20%		
5	PROCEDURES APPROPRIATE FOR PROTON THERAPY	19,163-25,551	19,039-25,386	19,280-25,706
6	PROCEDURE CAPACITY OF SHPC (UTILIZATION OF CAPACITY)	16,196	25,193	27,996
7	PERCENT OF SHPC PROCEDURES FROM PSA	60%		
8	SHPC PROCEDURES FROM PSA	9,718	15,116	16,798
9	SHPC MARKET SHARE OF PSA PROTON THERAPY PROCEDURES IN STEP 5	36.7%-48.9%	57.5%-76.6	63.7%-84.0%
10	SHPC MARKET SHARE OF PSA RADIATION THERAPY PROCEDURES	7.6%	11.9%	13.0%

13. Section C, Economic Feasibility, Item 2 (Funding) and Item 8 (Financial Viability)

Item 2 - The primary means of supporting the capital needs of the project from tax exempt bonds issued by the Industrial Development Board of Williamson County and underwritten by Deutsche Bank is noted. There is a note on the bottom of the Project Costs Chart on page 52 identifying \$91,719,789 as the "Applicant's and Developer's Capital costs". How was this amount determined?

This amount was determined by subtracting the Equipment Maintenance Cost from the Total Estimated Project Cost.

Since the amount falls below the \$110,000,000 of tax exempt bonds approved in the Williamson County Industrial Board's 1/15/2015 preliminary resolution, it appears that financial support from other sources may not be necessary to help fund the project. Is this consistent with the plans for funding the project?

Yes. The entire project will be funded with the bond proceeds. Therefore, financial support from other sources will not be necessary

Item 8 - Please explain and document the nature and scope of the amounts available from Reserve Accounts that are included in the applicant's financing model to assure adequate cash flow and viability.

The financing structure is modeled after the tax-exempt bond financing secured for the Provision Center for Proton Therapy in Knoxville. It provides for the establishment of a debt service reserve account in an amount equal to one year's debt service, estimated to be approximately \$9,270,000. This account will be funded from the bond proceeds. Debt service is almost half of the center's total cash expenses (excluding depreciation) in its first year of operation. Excluding the depreciation expense, the center is projected to be cash flow positive in the first year of operation. Further, although present uses of funds of \$106,724,669 will be required to fund the project, the Williamson County Industrial Development Board's resolution allowing for up to \$110,000,000 in bonds and Deutsche Bank's

commitment to fund the same provides a sufficient cushion should costs and expenses exceed projections. The Provision Center for Proton Therapy was completed at a cost that was approximately 0.3% above budget. Based on our experience, we expect the financial results for this project to be similar.

Do the aforementioned Reserve Accounts constitute the means to support the operating costs of the project, including repayment of the amounts owed to the equipment vendor per the schedule noted in the vendor's quote?

The reserve accounts do not support the operating costs of the center. Bond proceeds will cover 100% of the projected uses including equipment costs. Below is a chart itemizing the uses of the bond proceeds.

Uses:		
Building & Land		\$24,280,928
Equipment		\$50,831,450
Debt Service Reserve Fund		\$9,270,000
Capitalized Interest		\$5,690,199
Financing Fee		\$1,577,212
Start-Up Expenses/Pre Operating Expenses		\$15,074,880
		\$106,724,669

With respect to the amounts owed for the equipment installed in the facility, including the payments outlined in the vendor's quote, those amounts will be paid as they become due with the proceeds of the tax-exempt bonds. This amount is included in the total bond amount.

Do the Reserve Accounts require commitments and/or pledges by the applicant's LLC members prior to being utilized? Please discuss. In your response, it would be helpful to provide documentation in the form of audited financial statements that attests to the LLC member's ability to help support the project.

Should these recent audited financial statements not be available, please provide a statement from a banker or financial industry professional that attests to the applicant LLC's ability to financial support this project from reserve accounts, contributions from its members, or any other means that can be noted.

As indicated in prior responses, the cost of this project will be entirely financed through the issuance of tax-exempt bonds. Accordingly, financial support by the applicant LLC's members will be unnecessary.

The tax-exempt financing for this project mirrors the existing financing in place for the Provision Center for Proton Therapy. The reserve accounts for the present tax-exempt bond financing of the Provision Center for Proton Therapy in Knoxville do not require commitments and/or pledges by its LLC members prior to being utilized. Since the applicant will use a similar structure, we do not expect the financing to require commitments or pledges by the applicant LLC's members.

14. Section C, Economic Feasibility, Item 4 (Projected Data Chart)

The average gross rate is approximately \$2,000 per treatment higher than the rate identified for The Proton Therapy Center in Knoxville approved in CN1001-010A. Given the significantly high Medicare and Medicaid payor mix estimate at approximately 70 percent of total gross revenues in Year 1, what developments were taken into consideration in developing the rates used to project annual gross operating revenues in the chart?

The average gross rate calculated in 2010 was an estimate based on proton therapy rates in other states because rates had not yet been published by the Medicare Administrative Contractor for Tennessee. The actual gross rate per treatment in the initial year of the Provision Center for Proton Therapy in Knoxville was \$5,352.60. This data was used as the basis for determining the rate for the Scott Hamilton Proton Center which is within 0.5% of the gross rate per treatment experienced in Year One of the Provision Center Proton Therapy.

February 24, 2015**2:49 pm**

Please describe and provide the source used to project the \$2,849,334 principle expense and \$6,325,970 of interest expense totaling to \$9,175,304 in Year 1 of the project (CY2019). Where is the repayment/amortization schedule (terms) documented in the application attachments? Please clarify.

The Provision Center for Proton Therapy refinanced its bonds in August 2014 with terms similar to those projected for the Scott Hamilton Proton Center – 6.00% fixed interest rate and 20-year bond term. This was the source used to project the amortization schedule which appears on following the page.

Loan Amortization Schedule

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Loan Amount	\$ 106,724,669
Annual Interest Rate	6.000%
Term of Loan in Years	20
First Payment Date	1/1/2019
Frequency of Payment	Monthly

Summary

Rate (per period)	0.500%
Total Payments	\$183,506,081
Total Interest	\$76,781,412
Interest Savings	\$1

Payment (per period) \$764,608.68**Amortization Schedule**

No.	Due Date	Payment Due	Additional Payment	Interest	Principal	Balance
						106,724,669
1	1/1/2019	764,609		533,623	230,985	106,493,684
2	2/1/2019	764,609		532,468	232,140	106,261,543
3	3/1/2019	764,609		531,308	233,301	106,028,242
4	4/1/2019	764,609		530,141	234,467	105,793,775
5	5/1/2019	764,609		528,969	235,640	105,558,135
6	6/1/2019	764,609		527,791	236,818	105,321,317
7	7/1/2019	764,609		526,607	238,002	105,083,315
8	8/1/2019	764,609		525,417	239,192	104,844,123
9	9/1/2019	764,609		524,221	240,388	104,603,735
10	10/1/2019	764,609		523,019	241,590	104,362,145
11	11/1/2019	764,609		521,811	242,798	104,119,347
12	12/1/2019	764,609		520,597	244,012	103,875,335
13	1/1/2020	764,609		519,377	245,232	103,630,103
14	2/1/2020	764,609		518,151	246,458	103,383,645
15	3/1/2020	764,609		516,918	247,690	103,135,954
16	4/1/2020	764,609		515,680	248,929	102,887,025
17	5/1/2020	764,609		514,435	250,174	102,636,852
18	6/1/2020	764,609		513,184	251,424	102,385,427
19	7/1/2020	764,609		511,927	252,682	102,132,746
20	8/1/2020	764,609		510,664	253,945	101,878,801
21	9/1/2020	764,609		509,394	255,215	101,623,586
22	10/1/2020	764,609		508,118	256,491	101,367,096
23	11/1/2020	764,609		506,835	257,773	101,109,322
24	12/1/2020	764,609		505,547	259,062	100,850,260
25	1/1/2021	764,609		504,251	260,357	100,589,903
26	2/1/2021	764,609		502,950	261,659	100,328,244
27	3/1/2021	764,609		501,641	262,967	100,065,276
28	4/1/2021	764,609		500,326	264,282	99,800,994
29	5/1/2021	764,609		499,005	265,604	99,535,390
30	6/1/2021	764,609		497,677	266,932	99,268,459
31	7/1/2021	764,609		496,342	268,266	99,000,192

32	8/1/2021	764,609	495,001	269,608	98,730,584
33	9/1/2021	764,609	493,653	270,956	98,459,629
34	10/1/2021	764,609	492,298	272,311	98,187,318
35	11/1/2021	764,609	490,937	273,672	97,913,646
36	12/1/2021	764,609	489,568	275,040	97,638,606
37	1/1/2022	764,609	488,193	276,416	97,362,190
38	2/1/2022	764,609	486,811	277,798	97,084,392
39	3/1/2022	764,609	485,422	279,187	96,805,205
40	4/1/2022	764,609	484,026	280,583	96,524,623
41	5/1/2022	764,609	482,623	281,986	96,242,637
42	6/1/2022	764,609	481,213	283,395	95,959,242
43	7/1/2022	764,609	479,796	284,812	95,674,429
44	8/1/2022	764,609	478,372	286,237	95,388,193
45	9/1/2022	764,609	476,941	287,668	95,100,525
46	10/1/2022	764,609	475,503	289,106	94,811,419
47	11/1/2022	764,609	474,057	290,552	94,520,867
48	12/1/2022	764,609	472,604	292,004	94,228,863
49	1/1/2023	764,609	471,144	293,464	93,935,399
50	2/1/2023	764,609	469,677	294,932	93,640,467
51	3/1/2023	764,609	468,202	296,406	93,344,061
52	4/1/2023	764,609	466,720	297,888	93,046,172
53	5/1/2023	764,609	465,231	299,378	92,746,794
54	6/1/2023	764,609	463,734	300,875	92,445,920
55	7/1/2023	764,609	462,230	302,379	92,143,541
56	8/1/2023	764,609	460,718	303,891	91,839,650
57	9/1/2023	764,609	459,198	305,410	91,534,239
58	10/1/2023	764,609	457,671	306,937	91,227,302
59	11/1/2023	764,609	456,137	308,472	90,918,830
60	12/1/2023	764,609	454,594	310,015	90,608,815
61	1/1/2024	764,609	453,044	311,565	90,297,251
62	2/1/2024	764,609	451,486	313,122	89,984,128
63	3/1/2024	764,609	449,921	314,688	89,669,440
64	4/1/2024	764,609	448,347	316,261	89,353,179
65	5/1/2024	764,609	446,766	317,843	89,035,336
66	6/1/2024	764,609	445,177	319,432	88,715,904
67	7/1/2024	764,609	443,580	321,029	88,394,875
68	8/1/2024	764,609	441,974	322,634	88,072,240
69	9/1/2024	764,609	440,361	324,247	87,747,993
70	10/1/2024	764,609	438,740	325,869	87,422,124
71	11/1/2024	764,609	437,111	327,498	87,094,626
72	12/1/2024	764,609	435,473	329,136	86,765,490
73	1/1/2025	764,609	433,827	330,781	86,434,709
74	2/1/2025	764,609	432,174	332,435	86,102,274
75	3/1/2025	764,609	430,511	334,097	85,768,177
76	4/1/2025	764,609	428,841	335,768	85,432,409
77	5/1/2025	764,609	427,162	337,447	85,094,962
78	6/1/2025	764,609	425,475	339,134	84,755,829
79	7/1/2025	764,609	423,779	340,830	84,414,999
80	8/1/2025	764,609	422,075	342,534	84,072,465

81	9/1/2025	764,609	420,362	344,246	83,728,219
82	10/1/2025	764,609	418,641	345,968	83,382,251
83	11/1/2025	764,609	416,911	347,697	83,034,554
84	12/1/2025	764,609	415,173	349,436	82,685,118
85	1/1/2026	764,609	413,426	351,183	82,333,935
86	2/1/2026	764,609	411,670	352,939	81,980,996
87	3/1/2026	764,609	409,905	354,704	81,626,292
88	4/1/2026	764,609	408,131	356,477	81,269,815
89	5/1/2026	764,609	406,349	358,260	80,911,555
90	6/1/2026	764,609	404,558	360,051	80,551,505
91	7/1/2026	764,609	402,758	361,851	80,189,653
92	8/1/2026	764,609	400,948	363,660	79,825,993
93	9/1/2026	764,609	399,130	365,479	79,460,514
94	10/1/2026	764,609	397,303	367,306	79,093,208
95	11/1/2026	764,609	395,466	369,143	78,724,065
96	12/1/2026	764,609	393,620	370,988	78,353,077
97	1/1/2027	764,609	391,765	372,843	77,980,234
98	2/1/2027	764,609	389,901	374,708	77,605,526
99	3/1/2027	764,609	388,028	376,581	77,228,945
100	4/1/2027	764,609	386,145	378,464	76,850,481
101	5/1/2027	764,609	384,252	380,356	76,470,125
102	6/1/2027	764,609	382,351	382,258	76,087,867
103	7/1/2027	764,609	380,439	384,169	75,703,698
104	8/1/2027	764,609	378,518	386,090	75,317,607
105	9/1/2027	764,609	376,588	388,021	74,929,587
106	10/1/2027	764,609	374,648	389,961	74,539,626
107	11/1/2027	764,609	372,698	391,911	74,147,716
108	12/1/2027	764,609	370,739	393,870	73,753,845
109	1/1/2028	764,609	368,769	395,839	73,358,006
110	2/1/2028	764,609	366,790	397,819	72,960,187
111	3/1/2028	764,609	364,801	399,808	72,560,380
112	4/1/2028	764,609	362,802	401,807	72,158,573
113	5/1/2028	764,609	360,793	403,816	71,754,757
114	6/1/2028	764,609	358,774	405,835	71,348,922
115	7/1/2028	764,609	356,745	407,864	70,941,058
116	8/1/2028	764,609	354,705	409,903	70,531,155
117	9/1/2028	764,609	352,656	411,953	70,119,202
118	10/1/2028	764,609	350,596	414,013	69,705,189
119	11/1/2028	764,609	348,526	416,083	69,289,106
120	12/1/2028	764,609	346,446	418,163	68,870,943
121	1/1/2029	764,609	344,355	420,254	68,450,689
122	2/1/2029	764,609	342,253	422,355	68,028,334
123	3/1/2029	764,609	340,142	424,467	67,603,867
124	4/1/2029	764,609	338,019	426,589	67,177,278
125	5/1/2029	764,609	335,886	428,722	66,748,555
126	6/1/2029	764,609	333,743	430,866	66,317,689
127	7/1/2029	764,609	331,588	433,020	65,884,669
128	8/1/2029	764,609	329,423	435,185	65,449,484
129	9/1/2029	764,609	327,247	437,361	65,012,123

130	10/1/2029	764,609	325,061	439,548	64,572,575
131	11/1/2029	764,609	322,863	441,746	64,130,829
132	12/1/2029	764,609	320,654	443,955	63,686,874
133	1/1/2030	764,609	318,434	446,174	63,240,700
134	2/1/2030	764,609	316,204	448,405	62,792,295
135	3/1/2030	764,609	313,961	450,647	62,341,647
136	4/1/2030	764,609	311,708	452,900	61,888,747
137	5/1/2030	764,609	309,444	455,165	61,433,582
138	6/1/2030	764,609	307,168	457,441	60,976,141
139	7/1/2030	764,609	304,881	459,728	60,516,413
140	8/1/2030	764,609	302,582	462,027	60,054,387
141	9/1/2030	764,609	300,272	464,337	59,590,050
142	10/1/2030	764,609	297,950	466,658	59,123,392
143	11/1/2030	764,609	295,617	468,992	58,654,400
144	12/1/2030	764,609	293,272	471,337	58,183,063
145	1/1/2031	764,609	290,915	473,693	57,709,370
146	2/1/2031	764,609	288,547	476,062	57,233,308
147	3/1/2031	764,609	286,167	478,442	56,754,866
148	4/1/2031	764,609	283,774	480,834	56,274,031
149	5/1/2031	764,609	281,370	483,239	55,790,793
150	6/1/2031	764,609	278,954	485,655	55,305,138
151	7/1/2031	764,609	276,526	488,083	54,817,055
152	8/1/2031	764,609	274,085	490,523	54,326,532
153	9/1/2031	764,609	271,633	492,976	53,833,556
154	10/1/2031	764,609	269,168	495,441	53,338,115
155	11/1/2031	764,609	266,691	497,918	52,840,197
156	12/1/2031	764,609	264,201	500,408	52,339,789
157	1/1/2032	764,609	261,699	502,910	51,836,879
158	2/1/2032	764,609	259,184	505,424	51,331,455
159	3/1/2032	764,609	256,657	507,951	50,823,504
160	4/1/2032	764,609	254,118	510,491	50,313,013
161	5/1/2032	764,609	251,565	513,044	49,799,969
162	6/1/2032	764,609	249,000	515,609	49,284,360
163	7/1/2032	764,609	246,422	518,187	48,766,173
164	8/1/2032	764,609	243,831	520,778	48,245,395
165	9/1/2032	764,609	241,227	523,382	47,722,014
166	10/1/2032	764,609	238,610	525,999	47,196,015
167	11/1/2032	764,609	235,980	528,629	46,667,386
168	12/1/2032	764,609	233,337	531,272	46,136,115
169	1/1/2033	764,609	230,681	533,928	45,602,187
170	2/1/2033	764,609	228,011	536,598	45,065,589
171	3/1/2033	764,609	225,328	539,281	44,526,308
172	4/1/2033	764,609	222,632	541,977	43,984,331
173	5/1/2033	764,609	219,922	544,687	43,439,644
174	6/1/2033	764,609	217,198	547,410	42,892,234
175	7/1/2033	764,609	214,461	550,148	42,342,086
176	8/1/2033	764,609	211,710	552,898	41,789,188
177	9/1/2033	764,609	208,946	555,663	41,233,525
178	10/1/2033	764,609	206,168	558,441	40,675,084

179	11/1/2033	764,609	203,375	561,233	40,113,851
180	12/1/2033	764,609	200,569	564,039	39,549,811
181	1/1/2034	764,609	197,749	566,860	38,982,952
182	2/1/2034	764,609	194,915	569,694	38,413,258
183	3/1/2034	764,609	192,066	572,542	37,840,715
184	4/1/2034	764,609	189,204	575,405	37,265,310
185	5/1/2034	764,609	186,327	578,282	36,687,028
186	6/1/2034	764,609	183,435	581,174	36,105,855
187	7/1/2034	764,609	180,529	584,079	35,521,775
188	8/1/2034	764,609	177,609	587,000	34,934,775
189	9/1/2034	764,609	174,674	589,935	34,344,841
190	10/1/2034	764,609	171,724	592,884	33,751,956
191	11/1/2034	764,609	168,760	595,849	33,156,107
192	12/1/2034	764,609	165,781	598,828	32,557,279
193	1/1/2035	764,609	162,786	601,822	31,955,457
194	2/1/2035	764,609	159,777	604,831	31,350,625
195	3/1/2035	764,609	156,753	607,856	30,742,770
196	4/1/2035	764,609	153,714	610,895	30,131,875
197	5/1/2035	764,609	150,659	613,949	29,517,926
198	6/1/2035	764,609	147,590	617,019	28,900,907
199	7/1/2035	764,609	144,505	620,104	28,280,802
200	8/1/2035	764,609	141,404	623,205	27,657,598
201	9/1/2035	764,609	138,288	626,321	27,031,277
202	10/1/2035	764,609	135,156	629,452	26,401,825
203	11/1/2035	764,609	132,009	632,600	25,769,225
204	12/1/2035	764,609	128,846	635,763	25,133,463
205	1/1/2036	764,609	125,667	638,941	24,494,521
206	2/1/2036	764,609	122,473	642,136	23,852,385
207	3/1/2036	764,609	119,262	645,347	23,207,039
208	4/1/2036	764,609	116,035	648,573	22,558,465
209	5/1/2036	764,609	112,792	651,816	21,906,649
210	6/1/2036	764,609	109,533	655,075	21,251,573
211	7/1/2036	764,609	106,258	658,351	20,593,222
212	8/1/2036	764,609	102,966	661,643	19,931,580
213	9/1/2036	764,609	99,658	664,951	19,266,629
214	10/1/2036	764,609	96,333	668,276	18,598,354
215	11/1/2036	764,609	92,992	671,617	17,926,737
216	12/1/2036	764,609	89,634	674,975	17,251,762
217	1/1/2037	764,609	86,259	678,350	16,573,412
218	2/1/2037	764,609	82,867	681,742	15,891,670
219	3/1/2037	764,609	79,458	685,150	15,206,520
220	4/1/2037	764,609	76,033	688,576	14,517,944
221	5/1/2037	764,609	72,590	692,019	13,825,925
222	6/1/2037	764,609	69,130	695,479	13,130,446
223	7/1/2037	764,609	65,652	698,956	12,431,489
224	8/1/2037	764,609	62,157	702,451	11,729,038
225	9/1/2037	764,609	58,645	705,963	11,023,075
226	10/1/2037	764,609	55,115	709,493	10,313,581
227	11/1/2037	764,609	51,568	713,041	9,600,540

228	12/1/2037	764,609	48,003	716,606	8,883,934
229	1/1/2038	764,609	44,420	720,189	8,163,745
230	2/1/2038	764,609	40,819	723,790	7,439,956
231	3/1/2038	764,609	37,200	727,409	6,712,547
232	4/1/2038	764,609	33,563	731,046	5,981,501
233	5/1/2038	764,609	29,908	734,701	5,246,800
234	6/1/2038	764,609	26,234	738,375	4,508,425
235	7/1/2038	764,609	22,542	742,067	3,766,358
236	8/1/2038	764,609	18,832	745,777	3,020,581
237	9/1/2038	764,609	15,103	749,506	2,271,076
238	10/1/2038	764,609	11,355	753,253	1,517,822
239	11/1/2038	764,609	7,589	757,020	760,803
240	12/1/2038	764,607	3,804	760,803	(0)

The maintenance cost on page 136 of the 1/17/2015 vendor equipment quote is listed at \$12,688,000 in lieu of the \$14,008,000 amount shown in the chart. Please clarify.

The maintenance cost of \$12,688,000 is for the proton therapy equipment only. The difference is the maintenance cost of the ancillary equipment as noted in the Proton Therapy Equipment chart provided in B.II.E in Years Two – Five of the project.

What accounts for the 2 fold increase in other expenses? In your response, please also provide a breakout for those items in excess of \$50,000 or greater.

The increase is attributable to increases in cost for IT Expenses (increased cost due to increase in patients), Management and Billing Fees (as outlined in the draft management contract), and in Annual Equipment Maintenance (In Year One as noted in the Proton Therapy Equipment chart only the Proton Therapy equipment has a maintenance cost.)

<u>Other Expenses</u>	<u>2019</u>	<u>2020</u>
Facility Operating Expenses & Utilities	\$533,208	\$543,872
IT Expenses	\$202,613	\$314,856
Non-Physician Professional Fees	\$1,250,000	\$1,250,000
Management & Billing Fees	\$1,851,991	\$2,882,944
Medical Director Contract	\$100,000	\$100,000
Annual Equipment Maintenance	\$589,000	\$3,135,000

February 24, 2015**2:49 pm**

There appears to be 2 amounts provided for NOI Less Capital Expenditures in the chart. For example, it is unclear how the unfavorable NOI of -\$2,398,032 was determined for Year 1 (last entry at the bottom of the chart). Please clarify.

This was an error on our behalf. The last entry at the bottom of the chart was an internal calculation. The NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES for 2019 should be (\$5,247,366) and \$1,142,631 for 2020. We have deleted the last entry and a corrected chart is submitted following this page.

February 24, 2015

2:49 pm

PROJECTED DATA CHART— SCOTT HAMILTON PROTON CENTER

Give information for the two (2) years following the completion of this proposal.

The fiscal year begins in January.

		CY 2019	CY 2020
	Patients	549	854
	Treatments	16,196	25,193
A.	Utilization Data		
B.	Revenue from Services to Patients		
1.	Inpatient Services	\$	\$
2.	Outpatient Services	87,063,885	135,295,618
3.	Emergency Services		
4.	Other Operating Revenue (Specify)		
	Gross Operating Revenue	\$ 87,063,885	\$ 135,295,618
C.	Deductions for Operating Revenue		
1.	Contractual Adjustments	\$ 65,297,916	\$ 101,471,715
2.	Provision for Charity Care	544,149	845,598
3.	Provisions for Bad Debt	544,149	845,598
	Total Deductions	\$ 66,386,214	\$ 103,162,911
	NET OPERATING REVENUE	\$ 20,677,671	\$ 32,132,707
D.	Operating Expenses		
1.	Salaries and Wages	\$ 5,206,078	\$ 5,900,222
2.	Physicians Salaries and Wages		
3.	Supplies	1,318,699	2,049,234
4.	Taxes		
5.	Depreciation	5,483,145	5,483,145
6.	Rent		
7.	Interest, other than Capital	180,000	120,000
8.	Management Fees		
a.	Fees to Affiliates	1,851,991	2,882,944
b.	Fees to Non-Affiliates		
9.	Other Expenses (Specify)	2,709,820	5,379,227
	Utilities, IT, Professional Fees, Medical Director Fees, Annual Equipment Maintenance		
	Total Operating Expenses	\$ 16,749,733	\$ 21,814,772
E.	Other Revenue (Expenses) -- Net (Specify)	\$	\$
	NET OPERATING INCOME (LOSS)	\$ 3,927,938	\$ 10,317,935
F.	Capital Expenditures		
1.	Retirement of Principal	\$ 2,849,334	\$ 3,025,075
2.	Interest	6,325,970	6,150,229
	Total Capital Expenditures	\$ 9,175,304	\$ 9,175,304
	NET OPERATING INCOME (LOSS)	\$ -5,247,366	\$ 1,142,631
	LESS CAPITAL EXPENDITURES		

15. Section C, Economic Feasibility, Item 5.

Based on the amounts budgeted for professional fees in "Other Expenses" (Line D.9 of the Projected Data Chart), it appears that the average gross charge of \$5,376 per treatment in Year 1 may be a global fee, inclusive of both technical and professional fees. Please briefly describe in more detail.

The amounts budgeted for Professional Fees are for Non-Physician Related Professional Fees. The average gross charge of \$5,376 per treatment in Year One is a technical fee only.

16. Section C. II. Economic Feasibility, Question 10.

The Operating and Balance Statements for the new applicant LLC are noted. Given its formation on 12/18/14, please provide a brief summary of how the LLC intends to financially sustain operations with financial support from its members, lending institutions, etc. (*note: the summary should touch on the points noted in the response to Question # 13 above.*)

The applicant intends to finance the development of the Scott Hamilton Proton Center through the sale of tax-exempt bonds issued by the Williamson County Industrial Development Board without any contributions from the applicant LLC's members. Currently, uses of cash are projected to be \$106,724,669. The applicant will include certain start-up costs and capitalize interest and principal during the start-up phase to limit the cash burden during the initial operating period when revenue is lowest. The project is expected to generate positive cash flow in year one of its operation. Please see the responses to Question #13, above.

17. Section C, Contribution to Orderly Development, Items 3 and 4

Item 3 – It appears that the applicant projects a salaries and wages expense of \$5,206,078 in the Projected Data Chart for Year 1. Review of the staffing schedule on page 65 revealed a cost range of \$3,247,500 to \$4,177,500 for 48.5 total FTES. Please describe what accounts for the difference in the amounts.

The difference in the salaries and wages in the Projected Data Chart and the Staffing Plan is related to the fact that benefits and bonuses are not included in the Staffing Plan. The Staffing Plan only includes normal base salaries.

Item 3 - Given the projected utilization and the size of service area, what factors were taken into consideration in developing the staffing plan based on Provision Trust's experience with its proton therapy center operations in Knoxville? What were the "Lessons Learned" by Provision Trust in recruiting qualified and trained staff for the center within budget and on time?

The staffing plan was developed based upon the initial year of experience for staffing at the Provision Center for Proton Therapy. The Scott Hamilton Proton Center will follow the same successful staffing model of hiring individuals in each position who have experience in proton therapy. These experienced individuals at each position can assist in the training of other radiation oncology professionals whose proton therapy experience is limited.

Item 4 - With the volume of patients projected, how many Radiation Oncologists will need to be recruited and credentialed for medical staff privileges at the Proton Therapy Center? What is the size of the pool of qualified radiation oncologists in the service area with experience and/or training in proton therapy?

Based on the experience of the Provision Center for Proton Therapy in Knoxville a radiation oncologist is needed for every 22-25 patients under active treatment. In Year Two it is projected that 4-5 radiation oncologists will be required for the Scott Hamilton Proton Center. The size of the pool of radiation oncologists qualified to practice proton therapy in the Primary Service Area is limited. The center will have two options to pursue in recruiting and credentialing physicians. Radiation oncologists in the PSA can be trained at the new Provision Proton Therapy Training Center in Knoxville or a national search can be performed as has been the case at the Provision Center for Proton Therapy in Knoxville.

February 24, 2015**2:49 pm****18. Section C, Contribution to Orderly Development, Item 7.b**

It is unclear how or why the applicant expects to receive TennCare certification from the Tennessee Department of Health (TDH). Please clarify by correcting the response for this item.

The Provision Center for Proton Therapy in Knoxville has not received TennCare certification, but has treated TennCare referrals out of contract, on a preapproved basis. Both the Knoxville program and the proposed Middle Tennessee program will follow that policy until certification and MCO contracts are achieved. The applicant does not feel that TennCare patients in Tennessee should have less access to this important modality than Medicare and commercial patients.

This completes are responses to your supplemental questions. Please let me know if you have any questions.

Respectfully,



R. Scott Warwick
Vice President
MTPC, LLC.
6450 Provision Cares Way
Knoxville, TN 37909

February 24, 2015

2:49 pm

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY:

Scott Hamilton Proton Center

I, Scott Warwick, after first being duly sworn, state under oath that I am the lawful agent of the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete to the best of my knowledge.

R. Scott Warwick
Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 24 day of February, 2015
witness my hand at office in the County of KNOX, State of Tennessee.

Deborah F. Gunter
NOTARY PUBLIC

My commission expires

February 5, 2017

Supplemental #2 -Copy-

Scott Hamilton Proton
Therapy Center

CN1502-004

February 27, 2015**9:07 am**

February 27, 2015

Jeff Grimm
HSDA Examiner
Tennessee Health Services and Development Agency
9th Floor, 502 Deaderick Street
Nashville, TN 37243

RE: Certificate of Need Application CN1502-004
Scott Hamilton Proton Therapy Center

Dear Mr. Grimm:

This letter responds to your recent request for additional information on this application. The items below are numbered to correspond to your questions. They are provided in triplicate, with affidavit.

1. Section B, Project Description, Item ILE.

Item 1.a.1 (cost) –

The response is noted.

However, the instructions found in Item 3 page 32 of the application ask for a quote or proposal from an equipment vendor. In order to compare the amounts the applicant identifies in the Project Cost Chart and the table on page 33, please help facilitate the confirmation of the base equipment cost by providing the dollar equivalent of the 5,490,000,000 Japanese Yen amount in the 1/17/2015 vendor quote.

The costs for shipping and installation appear to have been omitted from the \$64,839,450 equipment amount shown in the table as "CON Cost" and in the Project Cost Chart. The following definition regarding major medical equipment cost in Tennessee Health Services and Development Agency Rule 0720-9-.01 (13)(b) states " The cost of major medical equipment includes all costs, expenditures, charges, fees, and assessments which are reasonably necessary to put the equipment into use for the purposes for which the equipment was intended. Such costs specifically include, but are not necessarily limited to the following: maintenance agreements, covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding."

Please clarify the CON cost of the equipment by identifying the US dollar amount of the cost in the vendor quote. Please also confirm that the estimated total equipment cost of the project complies with Agency Rule by identifying the additional costs pertaining to shipping, government assessment (such as tariff on

entry of equipment to US), and installation. If the amount is different than the entry for the Project Costs Chart, please revise the chart and submit a replacement page 52-R with your response.

The price for the proton therapy equipment in the vendor's quote is 5,490,000,000 Japanese Yen. Applying the exchange rate that was effective when the application was prepared, yields a proton therapy equipment cost of \$46,700,000 as reflected in Table 1. The figure (\$47,531,450) in the first row of the proton therapy equipment cost table at page 33 of the application is the sum of the equipment cost converted to U.S. dollars and the U.S. medical device tax of \$831,450 as shown in Table 1, below.

	Table 1		Table 2
	As Filed		As of 2/26/15
	Proton Equipment		Proton Equipment
YEN	5,490,000,000	YEN	5,490,000,000
Conversion Rate Applied	0.0085	Conversion Rate Applied	0.0084
US \$	46,700,000	US \$	46,116,000
US Medical Device Tax	831,450	US Medical Device Tax	821,052
Total	47,531,450	Total	46,937,052

Applying the currency exchange rate as of February 26, 2015, to the quoted equipment cost of 5,490,000,000 Japanese Yen, yields a reduced proton therapy equipment cost of \$46,116,000 as shown in Table 2, above. Adding the medical device tax in the sum of \$821,052 yields a total equipment cost of \$46,937,052 as shown in Table 2. Since the exchange rate fluctuates almost daily, we have conservatively retained the equipment cost figures in the original application and as calculated in Table 1.

Shipping costs were included in the Vendor's Budgetary Quotation as reflected by the chart on page 9 of the quotation (page 129 of the application).

Note that in the section entitled "Transportation and Storage", shipping from the vendor's facility to the U.S.A., unloading and inland transportation within the U.S. are all noted as Sumitomo's responsibility as part of the quoted price.

Based on the experience of other proton centers importing specialized medical equipment and Provision's for the Provision Center for Proton Therapy there will be no government assessment fee (customs clearance, import duties, tariffs, etc.). Because the center is a not-for-profit center that is purchasing a needed medical service that is scarce in the United States, negotiation with U.S. Customs authorities has resulted in no cost to import proton therapy equipment.

Installation costs were, in fact, omitted from the vendor's quote in contemplation of the fact that a local proton therapy equipment manufacturer, ProNova Solutions, LLC, is expected to perform the installation. Since ProNova is an East Tennessee company, the cost of having their personnel perform the installation results in significant savings to the applicant. ProNova's quotation for the installation work appears on the following pages.

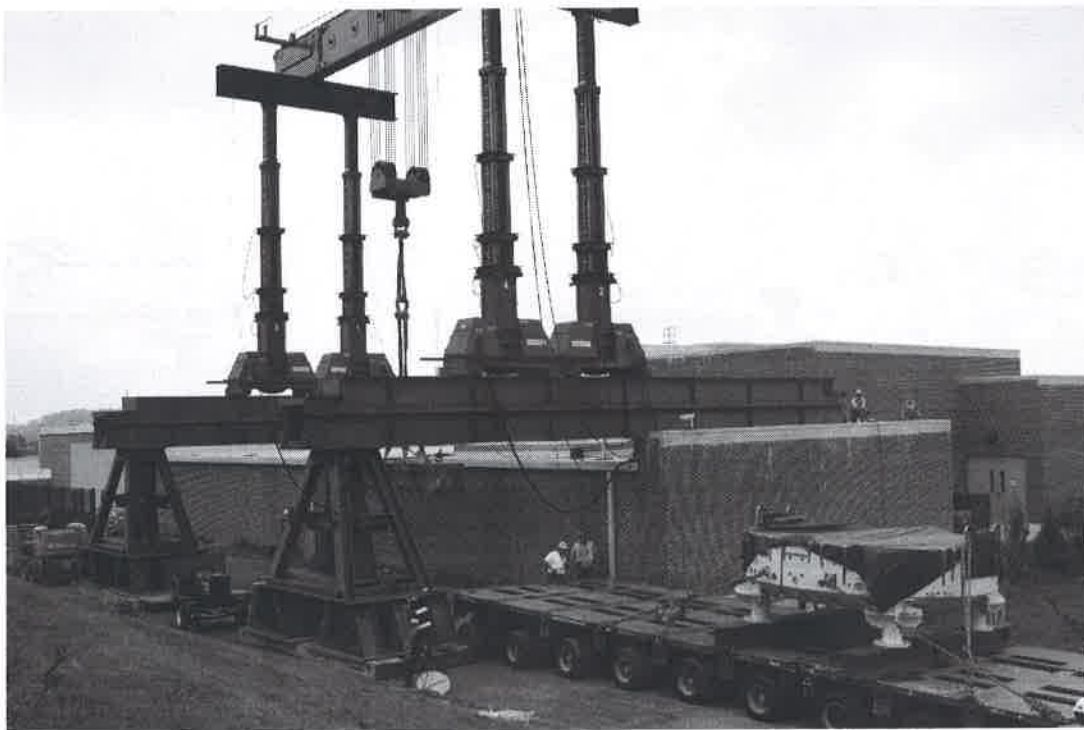


REDEFINING THE FUTURE OF CANCER TREATMENT

**Installation and Commissioning for Sumitomo 3-Room
Proton Therapy System**

Budgetary Quote # SUM001

1/30/15



Quotation for:

**Scott Warwick
MTPC, LLC
2095 Lakeside Centre, Suite 101
Knoxville, TN 37922**

Please address inquiries and replies to:

**Michael Bozeman
ProNova Solutions, LLC
330 Pellissippi Place
Maryville, TN 37804
865.712.3303**



Proton Therapy System Installation – Sumitomo (2 Gantries & 1 Fixed Beam)

The following figures are based upon the installation of Sumitomo Heavy Industries proton therapy equipment as described in their quotation Ref. No. Budgetary-S001-01 dated January 17, 2015.

Installation and Commissioning

- Site Planning drawings	\$103,667
- Project management	\$123,542
- Cyclotron and Gantries Installation Labor	\$901,889
- Mechanical Installation	\$528,063
- Electrical Installation and wiring	\$787,500
- System Commissioning	\$283,005

Cyclotron and Gantry Rigging

- Local Crane Contractor	\$ 96,269
- Cyclotron Rigging	\$229,944
- All other Rigging	\$265,588
- Debris Removal	\$ 10,408

Total: **\$3,329,875 USD**

ProNova Solutions is pleased to submit this quote for the service described herein, subject to the enclosed Terms and Conditions for the Sale of Products and Services, and the following:

- **Delivery Terms**
 - Installation timeline and Acceptance Dates to be finalized upon order execution.
- **Prices**
 - All prices are net, payable in USD.
- **Validity**
 - Quote Expiration Date: 7/30/15
- **Reservations**
 - The information contained in this document is proprietary and confidential. Any use and/or distribution of the material contained herein is strictly prohibited without prior written approval of ProNova.
- **Financial Terms:**
 - Based on percentage of completion
- **Detailed Terms and Conditions**
 - Other than the conditions contained herein shall be specified at the time of the Contract

February 27, 2015**9:07 am**

The installation costs were also omitted from the Project Cost Chart and the Proton Therapy Equipment Table which have been updated to include the amount set forth in the ProNova Quotation. A revised Project Cost Chart and Proton Therapy Equipment Table appear on the following pages. This revised Project Cost Chart will replace the original Project Cost Chart at page 52 of the application and the revised Proton Therapy Equipment Table on page 33 of the application.

February 27, 2015**9:07 am****PROJECTS COST CHART - SCOTT HAMILTON PROTON CENTER****A. Construction and equipment acquired by purchase:**

1. Architectural and Engineering Fees	\$789,651
2. Legal, Administrative, Consultant Fees (Excl CON Filing)	\$25,000
3. Acquisition of Site	\$3,750,000
4. Preparation of Site	\$1,221,150
5. Construction Cost	\$17,306,081
6. Contingency Fund	\$1,214,046
7. Fixed Equipment (PT)	\$54,161,325
8. Moveable Equipment (List all equipment over \$50,000)	\$0
9. Other (Specify) Maintenance (PT)	\$14,008,000

B. Acquisition by gift, donation, or lease:

1. Facility (inclusive of building and land)	\$0
2. Building only	0
3. Land only	0
4. Equipment (Specify)	0
5. Other (Specify)	0

C. Financing Costs and Fees:

1. Interim Financing	5,690,199
2. Underwriting Costs	1,577,212
3. Reserve for One Year's Debt Service	9,270,000
4. Other (Specify)	0

**D. Estimated Project Cost
(A+B+C)****\$109,012,664****E. CON Filing Fee****\$45,000****F. Total Estimated Project Cost (D+E)****\$109,057,664****Applicant & Developer's Capital Costs****\$95,049,664**

SUPPLEMENTAL #2**February 27, 2015****9:07 am**

Proton Therapy Equipment					
Modality	Cost	Service/Year	Service Yr 1	Service Yrs 2-5	CON COST
PT Eqpt (Cyclotron & Rooms)	\$47,531,450	\$0	\$589,000	\$12,099,000	\$60,219,450
Installation & Rigging	\$3,329,875				\$3,329,875
Treatment Planning System	\$1,000,000	\$100,000	\$0	\$400,000	\$1,400,000
Oncology Information System	\$800,000	\$80,000	\$0	\$320,000	\$1,120,000
Simulator	\$600,000	\$60,000	\$0	\$240,000	\$840,000
Miscellaneous Equipment (Dosimetry, Gating, Other)	\$900,000	\$90,000	\$0	\$360,000	\$1,260,000
TOTAL	\$54,161,325	\$330,000	\$589,000	\$13,419,000	\$68,169,325

SUPPLEMENTAL #2**February 27, 2015****9:07 am**

Please note that the installation cost was included in the Uses chart that appears at page 49 of the applicant's response to the Agency's supplemental questions. Installation was included within the Start-Up Expenses/Pre Operating Expenses ("Start-Up Expenses"). The Uses chart has also been updated by shifting the installation expense from the Start-Up Expenses line to the Equipment line. Accordingly, the total Uses and the amount of the bond financing remain the same. A copy of the revised Uses Chart appears below. This chart replaces the chart at page 49 of the applicant's responses to supplemental questions.

Uses:		
	Building & Land	\$24,280,928
	Equipment	\$54,161,325
	Debt Service Reserve Fund	\$9,270,000
	Capitalized Interest	\$5,690,199
	Financing Fee	\$1,577,212
	Start-Up Expenses/Pre Operating Expenses	\$11,745,005
		\$106,724,669
	Total Uses	\$106,724,669

2. Section B, Project Description, Item II.E

The response for Item 1.a.3 pertaining to clinical applications is noted. Review of the Medicare Administrative Contractor reference material pertaining to coverage for proton beam therapy provided in the response to question 4 (Cahaba Government Benefit Administrators L33070 effective 8/15/2013) appears to indicate that patients with Group 2 medical conditions, including prostate cancer and breast cancer, may be covered subject to the provision that the patient is enrolled in a clinical trial or national/regional clinical registry. Please describe the arrangements that will pertain to coordinating the patient's treatment regimen in this regard, including the process that will be followed to document same in the patient's clinical record/progress notes.

The Scott Hamilton Proton Center will participate in a regional proton therapy regional trial that is sponsored by the Center for Biomedical Research (CBR). CBR is a clinical research sponsor and site management company owned by Provision Healthcare and based in Knoxville (see Provision Group organization chart submitted in response to supplemental question 1.) The registry trial, "Registry Study for Proton Therapy Clinical Outcomes and Long-Term Follow-up" is currently listed on the National Institutes of Health's ClinicalTrials.gov. The registry trial identifier is NCT02070328. The registry trial accrues proton therapy patients who agree to allow their proton therapy treatment information to be collected prospectively for clinical research studies that may be performed in the future. Similar to the arrangement at the Provision Center for Proton Therapy in Knoxville, CBR will provide a Clinical Research Coordinator at the Scott Hamilton Proton Center to manage the registry trial which includes collecting all necessary data required by the registry and to assure that all clinical research records are appropriately documented.

3. Section C, Need, Item 1

The responses are noted. With respect to Megavoltage Radiation Therapy Service, please address the following:

Item 6.e – what is the accreditation status of Provision’s proton therapy center in Knoxville with the American College of Radiation Oncology? Is it reasonable to expect that the applicant LLC’s experience will be similar?

The Provision Center for Proton Therapy (PCPT) in Knoxville is currently preparing an application for submission for accreditation with the American College of Radiation Oncology (ACRO). There are several prerequisites that must be completed before a radiation oncology/proton therapy facility can submit an application. This includes the center treating a defined number of indications as well as assurance the center meets certain guidelines and standards as outlined by ACRO. PCPT has an ACRO Accreditation Team in place that includes leaders from each department. This team meets biweekly to review progress towards meeting the guidelines and standards in preparation to submit an application by the fourth quarter of 2015.

The Scott Hamilton Proton Center as noted in the application plans to seek ACRO accreditation and will follow the same process that is currently being utilized by PCPT.

4. Section C, Economic Feasibility, Item 2 (Funding) and Item 8 (Financial Viability)

The description of the funding support from the tax exempt bonds and clarification of the Reserve Accounts included in the applicant’s financing model to assure adequate cash flow and viability is noted. Please include a description that addresses the anticipated investment grade bond rating from Moody’s and Standard and Poor’s that may apply. Documentation of same in the form of an addendum to the 12/23/14 letter from Deutsche Bank Securities, Inc. (or memo) would be helpful in this regard.

The bonds issued by the Williamson County Industrial Development Board will not be rated initially. Like the bonds for the Provision Center for Proton

February 27, 2015**9:07 am**

Therapy, the applicant's bonds will be sold without a public rating and sold only to accredited investors.

5. Section C. II. Economic Feasibility, Question 9.

In the response to Item 4 (Section A, Item13) and Item 18 of your 2/24/15 supplemental response, the applicant notes that TennCare MCOs are currently providing coverage on a case by case basis and the Provision Center in Knoxville is treating TennCare referrals out of contract on a preapproved basis.

As such, how was the estimated \$4.4 million in gross revenue determined for the 5% TennCare payor mix estimate on page 60 of the application? In your response, please estimate gross revenues for all payors in Year 1 of the project by completing the table below.

The estimate was based on the premise that in 2019 the TennCare MCOs will contract with the new facility based on continued evidence development of the benefits of proton therapy. Please find a table below demonstrating the gross revenue and average net charge per treatment information as requested.

SHPTC Payor Source, Year 1			
Payor Source	Gross Revenue	Gross Revenue By Payor Source	Average Net Charge Per Tx
Medicare	\$56,591,525	65%	\$1,166
TennCare	\$4,353,194	5%	\$921
Managed Care*	\$0	0%	
Commercial	\$8,706,389	10%	\$1,749
International/Self-Pay	\$17,412,777	20%	\$1,749
Other	\$0	0%	
Total	\$87,063,885	100%	\$1,277
*Grouped with Commercial			

February 27, 2015

9:07 am

This completes are responses to your additional supplemental questions. Please let me know if you have any questions.

Respectfully,

A handwritten signature in black ink that reads "R. Scott Warwick". The signature is written in a cursive, flowing style.

R. Scott Warwick
Vice President
MTPC, LLC.
6450 Provision Cares Way
Knoxville, TN 37909

February 27, 2015

9:07 am

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY:

Scott Hamilton Proton Center

I, R. Scott Warwick, after first being duly sworn, state under oath that I am the lawful agent of the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete to the best of my knowledge.

R. Scott Warwick
Signature/Title
CONSULTANT

Sworn to and subscribed before me, a Notary Public, this the 26 day of Feb, 2015,
witness my hand at office in the County of KNOX, State of Tennessee.

My commission expires

February 5, 2017





State of Tennessee
Health Services and Development Agency

Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

February 18, 2015

Scott Warwick
MTPC, LLC
6450 Provision Cares Way
Knoxville, TN 37909

RE: Certificate of Need Application CN1502-004

Scott Hamilton Proton Therapy Center

Dear Mr. Warwick:

This will acknowledge our February 10, 2015 receipt of your application for a Certificate of Need for the establishment of a proton therapy center for cancer patients, the acquisition of major medical equipment and the initiation of outpatient proton therapy services in a new building to be constructed at an unaddressed site containing approximately 11.6 acres located on the east side of Carothers Parkway between its intersection with Physician's Way and Williamson Medical Center in Franklin (Williamson County), TN.

Several items were found which need clarification or additional discussion. Please review the list of questions below and address them as indicated. The questions have been keyed to the application form for your convenience. I should emphasize that an application cannot be deemed complete and the review cycle begun until all questions have been answered and furnished to this office.

Please submit responses in triplicate by 4:00 PM, February 25, 2015. If the supplemental information requested in this letter is not submitted by or before this time, then consideration of this application may be delayed into a later review cycle.

1. Section A, Applicant Profile, Items 3 and 4

Please provide an organization chart which shows the ownership and business relationships between MTPC, LLC, the management company, the real estate development company, the financing entities and any other companies within the Provision family of companies. Please also identify all members of MTPC, LLC with ownership interests of 5% or greater

2. Section A, Applicant Profile, Item 5

Your response is noted. Please briefly describe the background and experience of the management company and its executives in proton beam therapy, including the manager's participation in the operation of the new proton center approved and implemented in CN1002-010A.

3. Section A, Applicant Profile, Item 6

Please provide documentation of ownership of the unaddressed 11.6 acre site for the proposed facility as described in the 1/16/2015 signed real estate purchase agreement on page 103 of the application (parcel 48.04, Williamson County tax map 079). Please briefly describe the relationship between the seller (trustee noted in document) and the owner of record of the property.

It appears that MTPC LLC's representative (Michael Sommi, Secretary) signing the Assignment and Assumption Agreement from the entity originally purchasing the land (Amence Development, LLC) has been appropriately authorized by each of the applicant LLC's 3 members to obligate the applicant to said agreement. Is there a resolution or similar document that reflects the LLC board or members' formal approval in this regard? Please briefly describe the process that applies to the agreement for the acquisition of the real estate.

It would be helpful to have some clarification of the various business entities that are involved in the acquisition of the property for the proposed facility. Please identify the member ownership and percentage of each member's ownership, and the business relationships between MTPC, LLC (inclusive of Provision Trust, Inc., and the 2 other current members) and Amence Development, LLC.

Regarding the purchase contract between the seller and Amence Development, LLC, please confirm the total purchase price of the 11.6 undeveloped acreage of the site, which is listed as \$7,326,792 in the notes on page 50 to the Project Costs Chart in the application. Please also confirm the purchase price amount that applies to the 1/22/15 Assignment and Assumption Agreement between the Amence Development, LLC and the applicant LLC.

Review of the Closing Date provisions in the 1/16/15 purchase agreement revealed a maximum period of not more than 210 days or 7 months ending on or about August 17, 2015 for formal conveyance of the property. If the closing date is delayed to August 2015, it appears that the applicant LLC will not have control of the site on the date of the HSDA Board's hearing of the application on or about May 27, 2015. Please explain what measures might be taken to minimize extensions to the closing date on the property.

4. Section A, Applicant Profile, Item 13

The response is noted. Given Provision Trust, Inc.'s controlling membership interest in the applicant LLC and "lessons learned" from its operation of the Provision Center for Proton Therapy in Knoxville approved in CN1001-010A, please provide an update regarding coverage of proton therapy services under Medicare, TennCare, and other state's Medicaid programs within the applicant's proposed service area.

Please also describe coverage that is available for proton therapy services through the major commercial health insurance companies in the applicant's proposed service area. What is their typical reimbursement for these services?

5. Section B, Project Description, Item IL A.

As the applicant has noted, many of the current proton therapy centers appear to be affiliated with nationally renowned teaching hospitals. Is the applicant able to document interest of same through the Scott Hamilton CARES Foundation or the Provision Cares Foundation, Inc.? Please include a brief description explaining how the applicant will be able to benefit from potential affiliations with health care organization(s) such as the Monroe Carell Children's Hospital, Vanderbilt Ingram Cancer Center or Sarah Cannon Cancer Center organizations that have established and valued referral relationships throughout the proposed service area.

In terms of existing resources, it would be helpful to have a better understanding of how the applicant will utilize existing radiation therapy and diagnostic imaging services available in the service area as opposed to potentially duplicating same. Please discuss the applicant's intentions in this regard.

In terms of medical direction of the proposed center, review of Section 3.2 of the proposed management agreement between MTPC, LLC (applicant LLC) and Provision Proton Centers, LLC revealed that MTPC shall be responsible for appointing a medical director of the center. As such, please briefly discuss the arrangements that may be provided in this regard. Please also describe the process to be followed by the governing body of the applicant LLC to select and approve the most qualified candidate for the medical director position.

6. Section B, Project Description, Item IL C.

The description of proton therapy as the advanced form of radiation treatment available is noted. What excerpts can be provided from any of the studies included in the medical literature on page 21 (or other related sources) that justifies the higher cost of proton therapy over traditional radiation therapy by improved medical outcomes and/or reduced side effects? Please clarify.

What plans if any, does the applicant have to collaborate with existing linear accelerator radiation therapy service providers in the service area such that care coordination or continuity of care for patients of the center is available?

7. Section B, Project Description, Item ILE.

Item 1.a.1 (cost) - The total equipment cost is the same as reflected in both the table on page 33 and the Project Costs Chart on page 52. However, the amount in the vendor quote appears to be provided in Japanese Yen equivalents (JP¥ 5,490,000,000) and excludes costs for a treatment planning system, an oncology information system, shipping and taxes. Please clarify by documenting that the amounts in the vendor quote support what is identified in the Project Cost Chart cost for the unit. As a suggestion, it would be helpful to provide written documentation from the vendor to clarify, such as an addendum to the quote provided with the application.

Item 1.a.3 - Please identify the primary clinical applications that apply to the service with brief description of a typical course of treatment, as appropriate. In your discussion, please summarize how the course of treatment compares between a proton therapy service and a linear accelerator service.

8. Section B, Project Description, Item IV (Floor Plan)

One of the 3 shielded patient treatment areas stations shown on the 1st Floor Plan is labeled Horizontal Beam Treatment Room while the other 2 are shown as Gantry Treatment Areas. The description provided on page 9 for Design and Space requirements mentions a fixed beam treatment room and 2 gantry rooms. Is the horizontal room the same as the fixed beam room? Please clarify.

9. Section C, Need, Item 1

It appears that responses to the 5 Principles in the State Health Plan were omitted from the application. Please include your response for this item.

Given the plans for construction of a new 36,083 square foot building for the outpatient proton therapy center at an estimated cost of approximately \$17,306,081, please also provide responses for the criteria pertaining to Construction and Renovation criteria in this section.

With respect to the responses provided for Megavoltage Radiation Therapy Service, please address the following:

Item 4 – It is understood that this criterion may not apply to the proposed proton therapy service. However, the response should also recognize the utilization of existing radiation therapy linear accelerator units in the 38 county TN service area. Please provide the utilization by provider for CY 2013 by contacting Alecia Craighead, HSDA Statistical Analyst III, for assistance in obtaining the data from the HSDA Equipment Registry.

Important Note: revised criteria for this standard has been developed and implemented by HSDA and TDH as part of the State Health Plan process. Please see Exhibit 1 at the end of this questionnaire for the template that applies to this standard.

10. Section C, Need, Item 4 (Service Area)

In terms of special needs, it would be helpful to have an appreciation of radiation therapy utilization by residents of the TN portion of the service area with comparison to the statewide average for TN. Please complete the table below using information from the HSDA Equipment Registry. Please contact Alecia Craighead, Stat III for assistance.

Radiation Therapy Utilization by Residents of 38-County TN Service Area

County	2011 procedures	2012 procedures	2013 Procedures	% Change '11-'13	2013 Use Rate per 1,000 Population
Bedford					
Cannon					
Statewide	368,821	371,223	361,834	-1.9%	48.7

11. Section C, Need, Item 5

The status of other CON approved proton therapy centers in Tennessee is noted. It appears that utilization of the Knoxville facility is expected to increase from 8,846 treatments in 2014 to 22,785 treatments in 2015. Please explain the factors driving such a large anticipated increase in patient volumes.

With respect to existing radiation therapy service providers in the proposed 38 county Tennessee portion of the service area, please complete the table below using data from the HSDA Equipment Registry. Please feel free to contact Alecia Craighead, Stat III for assistance with this request.

38-County TN Service Area Historical Utilization

Provider	# Units	2011 procedures	2012 Procedures	2013 procedures	% Change '11-13	Use by Residents of TN Service Area-CY2013

12. Section C, Need, Item 6 (Applicant's Projected Utilization)

Based on projected utilization for CY2020, it appears that the each patient would receive an average of approximately 30 treatments at roughly 26 total hours per year during his/her course of treatment. Please describe the factors that apply to this estimate such as the type of cancer, the size of the tumor and/or the degree of metastasis? In your response, please describe how the course of treatment estimate compares with rates of other similar providers in TN and other states.

It appears that the Thomson Healthcare cancer incidence data is based on the application of national use rates to the service area population. Since cancer incidence data for the Tennessee counties is available from the Tennessee Cancer Registry please identify and compare this data to your model for the Tennessee portion of your service area.

It should be noted that data pertaining to actual radiation therapy treatment utilization is available from the HSDA Equipment Registry. Given the 15%-20% rate assumption (% of radiation therapy treatments eligible for proton therapy) identified in your step-down methodology on page 45, how might this compare to the projected utilization of the proposed proton therapy unit when taking into account

radiation therapy utilization in the 38-county Tennessee PSA from the HSDA Equipment Registry for 2011 – 2013? Please provide a brief comparison in this regard.

13. Section C, Economic Feasibility, Item 2 (Funding) and Item 8 (Financial Viability)

Item 2 - The primary means of supporting the capital needs of the project from tax exempt bonds issued by the Industrial Development Board of Williamson County and underwritten by Deutsche Bank is noted. There is a note on the bottom of the Project Costs Chart on page 52 identifying \$91,719,789 as the "Applicant's and Developer's Capital costs". How was this amount determined?

Since the amount falls below the \$110,000,000 of tax exempt bonds approved in the Williamson County Industrial Board's 1/15/2015 preliminary resolution, it appears that financial support from other sources may not be necessary to help fund the project. Is this consistent with the plans for funding the project?

Item 8 - Please explain and document the nature and scope of the amounts available from **Reserve Accounts** that are included in the applicant's financing model to assure adequate cash flow and viability.

Do the aforementioned **Reserve Accounts** constitute the means to support the operating costs of the project, including repayment of the amounts owed to the equipment vendor per the schedule noted in the vendor's quote?

Do the **Reserve Accounts** require commitments and/or pledges by the applicant's LLC members prior to being utilized? Please discuss. In your response, it would be helpful to provide documentation in the form of audited financial statements that attests to the LLC member's ability to help support the project.

Should these recent audited financial statements not be available, please provide a statement from a banker or financial industry professional that attests to the applicant LLC's ability to financial support this project from reserve accounts, contributions from its members, or any other means that can be noted.

14. Section C, Economic Feasibility, Item 4 (Projected Data Chart)

The average gross rate is approximately \$2,000 per treatment higher than the rate identified for The Proton Therapy Center in Knoxville approved in CN1001-010A. Given the significantly high Medicare and Medicaid payor mix estimate at approximately 70 percent of total gross revenues in Year 1, what developments were taken into consideration in developing the rates used to project annual gross operating revenues in the chart?

Please describe and provide the source used to project the \$2,849,334 principle expense and \$6,325,970 of interest expense totaling to \$9,175,304 in Year 1 of the project (CY2019). Where is

the repayment/amortization schedule (terms) documented in the application attachments?
Please clarify.

The maintenance cost on page 136 of the 1/17/2015 vendor equipment quote is listed at \$12,688,000 in lieu of the \$14,008,000 amount shown in the chart. Please clarify.

What accounts for the 2 fold increase in other expenses? In your response, please also provide a breakout for those items in excess of \$50,000 or greater.

There appears to be 2 amounts provided for NOI Less Capital Expenditures in the chart. For example, it is unclear how the unfavorable NOI of -\$2,398,032 was determined for Year 1 (last entry at the bottom of the chart). Please clarify.

15. Section C, Economic Feasibility, Item 5.

Based on the amounts budgeted for professional fees in "Other Expenses" (Line D.9 of the Projected Data Chart), it appears that the average gross charge of \$5,376 per treatment in Year 1 may be a global fee, inclusive of both technical and professional fees. Please briefly describe in more detail.

16. Section C. II. Economic Feasibility, Question 10.

The Operating and Balance Statements for the new applicant LLC are noted. Given its formation on 12/18/14, please provide a brief summary of how the LLC intends to financially sustain operations with financial support from its members, lending institutions, etc. (*note: the summary should touch on the points noted in the response to Question # 13 above.*)

17. Section C, Contribution to Orderly Development, Items 3 and 4

Item 3 - It appears that the applicant projects a salaries and wages expense of \$5,206,078 in the Projected Data Chart for Year 1. Review of the staffing schedule on page 65 revealed a cost range of \$3,247,500 to \$4,177,500 for 48.5 total FTES. Please describe what accounts for the difference in the amounts.

Item 3 - Given the projected utilization and the size of service area, what factors were taken into consideration in developing the staffing plan based on Provision Trust's experience with its proton therapy center operations in Knoxville? What were the "Lessons Learned" by Provision Trust in recruiting qualified and trained staff for the center within budget and on time?

Item 4 - With the volume of patients projected, how many Radiation Oncologists will need to be recruited and credentialed for medical staff privileges at the Proton Therapy Center? What is the size of the pool of qualified radiation oncologists in the service area with experience and/or training in proton therapy?

18. Section C, Contribution to Orderly Development, Item 7.b

It is unclear how or why the applicant expects to receive TennCare certification from the Tennessee Department of Health (TDH). Please clarify by correcting the response for this item.

In accordance with Tennessee Code Annotated, §68-11-1607(c) (5), "...If an application is not deemed complete within sixty (60) days after written notification is given to the applicant by the agency staff that the application is deemed incomplete, the application shall be deemed void." **For this application the sixtieth (60th) day after written notification is April 23, 2015. If this application is not deemed complete by this date, the application will be deemed void.** Agency Rule 0720-10-.03(4) (d) (2) indicates that "Failure of the applicant to meet this deadline will result in the application being considered withdrawn and returned to the contact person. Re-submittal of the application must be accomplished in accordance with Rule 0720-10-.03 and requires an additional filing fee." Please note that supplemental information must be submitted timely for the application to be deemed complete prior to the beginning date of the review cycle which the applicant intends to enter, even if that time is less than the sixty (60) days allowed by the statute. The supplemental information must be submitted with the enclosed affidavit, which shall be executed and notarized; please attach the notarized affidavit to the supplemental information.

If all supplemental information is not received and the application officially deemed complete prior to the beginning of the next review cycle, then consideration of the application could be delayed into a later review cycle. The review cycle for each application shall begin on the first day of the month after the application has been deemed complete by the staff of the Health Services and Development Agency.

Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. § 68-11-1607(d):

- (1) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.*
- (2) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate*

of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have any questions or require additional information, please contact this office.

Sincerely,

A handwritten signature in cursive script, appearing to read "Philip Grimm".

Philip Grimm, HSDA Examiner

EXHIBIT 1

STATE HEALTH PLAN
CERTIFICATE OF NEED STANDARDS AND CRITERIA
FOR
MEGAVOLTAGE RADIATION THERAPY SERVICES

The Health Services and Development Agency (HSDA) may consider the following standards and criteria for applications seeking to provide Megavoltage Radiation Therapy (MRT) Services. Existing providers of MRT services are not affected by these standards and criteria unless they take an action that requires a new certificate of need (CON) for MRT services.

These standards and criteria are effective immediately as of December 21, 2011, the date of approval and adoption by the Governor of the State Health Plan changes for 2011. Applications to provide MRT services that were deemed complete by HSDA prior to this date shall be considered under the Guidelines for Growth, 2000 Edition.

Definitions

External Beam Radiation Therapy (EBRT). Radiation therapy delivered by an MRT Unit from outside the body.

Linear Accelerator. A type of EMRT Unit that delivers a beam of high energy x-rays (photon or electron particles) from an external source to the location of the patient's tumor and/or other tissue being irradiated. Linear accelerators may deliver conventional EBRT, intensity modulated radiation therapy, image-guided radiation therapy, and SRT services. Linear accelerators are the only MRT Unit type specifically listed in Tennessee Code Annotated Section 68-11-1607 (a)(4) as requiring a CON in order for services to be initiated.

Linear Accelerator Service Area Capacity: The estimate of the number of Linear Accelerator MRT units needed in a given service area, based upon an Optimal Capacity of 7,688 procedures per year.

MRT Procedure: Each discrete MRT treatment related to services performed on a single patient during a single visit, designated by CPT code. The Health Services and Development Agency (1-ISDA) shall be responsible for setting reporting requirements consistent with this definition, including the development of a selected set of CPT codes.

MRT Unit: Medical equipment that performs radiation therapy.

Proton Beam Therapy Unit. A type of EBRT MRT Unit that uses proton beams rather than photon beams. Although not specifically listed as requiring a CON, the cost of initiating proton beam therapy services likely falls above the capital expenditure threshold set forth in TCA Section 68-11-1607 (2).

Radiation Therapy. A medical procedure that allows non-invasive treatment of tumors and cancer cells using X-rays, gamma rays, and charged particles. The radiation may be delivered by a machine outside the body (external-beam radiation therapy), or it may come from radioactive material placed in the body near cancer cells (internal radiation therapy, also called brachytherapy).

Radiation Therapy is also known as Stereotactic Radiotherapy (SRT) when used to target lesions in the brain and as Stereotactic Body Radiotherapy (SBRT) when used to target lesions in the body.

Service Area: For linear accelerators that do not perform SRT or SBRT procedures, the contiguous counties representing a reasonable area in which an applicant intends to provide MRT services and in which at least 120,000 people reside and where the applicant is able to reach the optimal capacity set forth below. Otherwise, a Service Area shall be the contiguous counties representing a reasonable area in which an applicant intends to provide MRT services.

Standards and Criteria

1. Utilization Standards for MRT Units.

- a. Linear Accelerators not dedicated to performing SRT and/or SBRT procedures:

- i. Full capacity of a Linear Accelerator MRT Unit is 8,736 procedures, developed from the following formula: 3.5 treatments per hour, times 48 hours (6 days of operation, 8 hours per day, or 5 days of operation, 9.6 hours per day), times 52 weeks.
 - ii. Linear Accelerator Minimum Capacity: 6,000 procedures per Linear Accelerator MRT Unit annually, except as otherwise noted herein.
 - iii. Linear Accelerator Optimal Capacity: 7,688 procedures per Linear Accelerator MRT Unit annually, based on a 12% average downtime per MRT unit during normal business hours annually.
 - iv. An applicant proposing a new Linear Accelerator should project a minimum of at least 6000 MRT procedures in the first year of service in its Service Area, building to a minimum of 7,688 procedures per year by the third year of service and for every year thereafter.
- b. For Linear Accelerators dedicated to performing only SRT procedures, full capacity is 500 annual procedures.
- c. For Linear Accelerators dedicated to performing only SRT/SBRT procedures, full capacity is 850 annual procedures.
- d. An exception to the standard number of procedures may occur as new or improved technology and equipment or new diagnostic applications for Linear Accelerators develop. An applicant must demonstrate that the proposed Linear

Accelerator offers a unique and necessary technology for the provision of health care services in the proposed Service Area.

- e. Proton Beam MRT Units. As of the date of the approval and adoption of these Standards and Criteria, insufficient data are available to enable detailed utilization standards to be developed for Proton Beam MRT Units.

2. Need Standards for MRT Units.

- a. For Linear Accelerators not dedicated solely to performing SRT and/or SBRT procedures, need for a new Linear Accelerator in a proposed Service Area shall be demonstrated if the average annual number of Linear Accelerator procedures performed by existing Linear Accelerators in the proposed Service Area exceeds 6,000.
- b. For Linear Accelerators dedicated to performing only SRT procedures, need in a proposed Service Area shall be demonstrated if the average annual number of MRT procedures performed by existing Linear Accelerators dedicated to performing only SRT procedures in a proposed Service Area exceeds 300, based on a full capacity of 500 annual procedures.
- c. For Linear Accelerators dedicated to performing only SRT/SBRT procedures, need in a proposed Service Area shall be demonstrated if the average annual number of MRT procedures performed by existing Linear Accelerators dedicated to performing only SRT/SBRT procedures in a proposed Service Area exceeds 510, based on a full capacity of 850 annual procedures.
- d. Need for a new Proton Beam MRT Unit: Due to the high cost and extensive service areas that are anticipated to be required for these MRT Units, an applicant proposing a new Proton Beam MRT Unit shall provide information regarding the utilization and service areas of existing or planned Proton Beam MRT Units' utilization and service areas (including those that have received a CON), if they provide MRT services in the proposed Service Area and if that data are available, and the impact its application, if granted, would have on those other Proton Beam MRT Units.

- e. An exception to the need standards may occur as new or improved technology and equipment or new diagnostic applications for MRT Units develop. An applicant must demonstrate that the proposed MRT Unit offers a unique and necessary technology for the provision of health care services in the proposed Service Area.

3. Access to MRT Units.

- a. An MRT unit should be located at a site that allows reasonable access for residents of the proposed Service Area.
- b. An applicant for any proposed new Linear Accelerator should document that the proposed location of the Linear Accelerator is within a 45 minute drive time of the majority of the proposed Service Area's population.
- c. Applications that include non-Tennessee counties in their proposed Service Areas should provide evidence of the number of existing MRT units that service the non-Tennessee counties and the impact on MRT unit utilization in the non-Tennessee counties, including the specific location of those units located in the non-Tennessee counties, their utilization rates, and their capacity (if that data are available).

4. Economic Efficiencies. All applicants for any proposed new MRT Unit should document that lower cost technology applications have been investigated and found less advantageous in terms of accessibility, availability, continuity, cost, and quality of care.

5. Separate Inventories for Linear Accelerators and for other MRT Units.

A separate inventory shall be maintained by the HSDA for Linear Accelerators, for Proton Beam Therapy MRT Units, and, if data are available, for Linear Accelerators dedicated to SRT and/or SBRT procedures and other types of MRT Units.

6. Patient Safety and Quality of Care. The applicant shall provide evidence that any proposed MRT Unit is safe and effective for its proposed use.

- a. The United States Food and Drug Administration (FDA) must certify the proposed MRT Unit for clinical use.
- b. The applicant should demonstrate that the proposed MRT Units shall be housed in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.
- c. The applicant should demonstrate how emergencies within the MRT Unit facility will be managed in conformity with accepted medical practice. Tennessee Open Meetings Act and/or Tennessee Open Records Act.
- d. The applicant should establish protocols that assure that all MRT Procedures performed are medically necessary and will not unnecessarily duplicate other services.
- e. An applicant proposing to acquire any MRT Unit shall demonstrate that it meets the staffing and quality assurance requirements of the American Society of Therapeutic Radiation and Oncology (ASTRO), the American College of Radiology (ACR), the American College of Radiation Oncology (ACRO) or a similar accrediting authority such as the National Cancer Institute (CNI). Additionally, all applicants shall commit to obtain accreditation from ASTRO, ACR or a comparable accreditation authority for MRT Services within two years following initiation of the operation of the proposed MRT Unit.

- f. All applicants should seek and document emergency transfer agreements with local area hospitals, as appropriate. An applicant's arrangements with its physician medical director must specify that said physician be an active member of the subject transfer agreement hospital medical staff.
 - g. All applicants should provide evidence of any onsite simulation and treatment planning services to support the volumes they project and any impact such services may have on volumes and treatment times.
- 7. The applicant should provide assurances that it will submit data in a timely fashion as requested by the HSDA to maintain the HSDA Equipment Registry.
- 8. In light of Rule 0720-11.01, which lists the factors concerning need on which an application may be evaluated, and Principle No. 2 in the State Health Plan, "Every citizen should have reasonable access to health care," the HSDA may decide to give special consideration to an applicant:
 - a. Who is offering the service in a medically underserved area as designated by the United States Health Resources and Services Administration;
 - b. Who is a "safety net hospital" or a "children's hospital" as defined by the Bureau of TennCare Essential Access Hospital payment program; or
 - c. Who provides a written commitment of intention to contract with at least one TennCare MCO and, if providing adult services, to participate in the Medicare program.

Comments:

- 1. The Office of Health Planning recognizes the need to review MRT Services standards and criteria on a frequent basis due to the evolving nature of the technology involved.
- 2. It is anticipated that the Tennessee Cancer Registry data, maintained by the Department of Health, will in the future become available for use by applicants to support the need for new MRT Units.

**CONSTRUCTION, RENOVATION,
EXPANSION, & REPLACEMENT
OF
HEALTH CARE INSTITUTIONS**

CONSTRUCTION, RENOVATION, EXPANSION, AND REPLACEMENT OF HEALTH CARE INSTITUTIONS

1. Any project that includes the addition of beds, services, or medical equipment will be reviewed under the standards for those specific activities.
2. For relocation or replacement of an existing licensed health care institution:
 - a. The applicant should provide plans which include costs for both renovation and relocation, demonstrating the strengths and weaknesses of each alternative.
 - b. The applicant should demonstrate that there is an acceptable existing or projected future demand for the proposed project.
3. For renovation or expansions of an existing licensed health care institution:
 - a. The applicant should demonstrate that there is an acceptable existing demand for the proposed project.
 - b. The applicant should demonstrate that the existing physical plant's condition warrants major renovation or expansion.

Section C, Need, Item 1 (State Health Plan)

Please discuss how the proposed project will relate to the 5 Principles for Achieving Better Health of the State Health Plan. Each Principle is listed below with example questions to help the applicant in its thinking.

1. The purpose of the State Health Plan is to improve the health of Tennesseans.
 - a. How will this proposal protect, promote, and improve the health of Tennesseans over time?
 - b. What health outcomes will be impacted and how will the applicant measure improvement in health outcomes?
 - c. How does the applicant intend to act upon available data to measure its contribution to improving health outcomes?
2. Every citizen should have reasonable access to health care.
 - a. How will this proposal improve access to health care? You may want to consider geographic, insurance, use of technology, and disparity issues (including income disparity), among others.
 - b. How will this proposal improve information provided to patients and referring physicians?
 - c. How does the applicant work to improve health literacy among its patient population, including communications between patients and providers?
3. The State's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies, and the continued development of the State's health care system.
 - a. How will this proposal lower the cost of health care?
 - b. How will this proposal encourage economic efficiencies?
 - c. What information will be made available to the community that will encourage a competitive market for health care services?
4. Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers.

- a. How will this proposal help health care providers adhere to professional standards?
 - b. How will this proposal encourage continued improvement in the quality of care provided by the health care workforce?
- 5. The state should support the development, recruitment, and retention of a sufficient and quality health care workforce.*
 - a. How will this proposal provide employment opportunities for the health care workforce?
 - b. How will this proposal complement the existing Service Area workforce?



State of Tennessee

Health Services and Development Agency

Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243

www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

February 25, 2015

Scott Warwick
MTPC, LLC
6450 Provision Cares Way
Knoxville, TN 37909

RE: Certificate of Need Application CN1502-004

Scott Hamilton Proton Therapy Center

Dear Mr. Warwick:

This will acknowledge our February 24, 2015 receipt of your supplemental response regarding your application for a Certificate of Need for the establishment of a proton therapy center for cancer patients, the acquisition of major medical equipment and the initiation of outpatient proton therapy services in a new building to be constructed at an unaddressed site containing approximately 11.6 acres located on the east side of Carothers Parkway between its intersection with Physician's Way and Williamson Medical Center in Franklin (Williamson County), TN.

Several items were found which need clarification or additional discussion. Please review the list of questions below and address them as indicated. The questions have been keyed to the application form for your convenience. I should emphasize that an application cannot be deemed complete and the review cycle begun until all questions have been answered and furnished to this office.

Please submit responses in triplicate by 1:00PM, February 27, 2015. If the supplemental information requested in this letter is not submitted by or before this time, then consideration of this application may be delayed into a later review cycle.

1. Section B, Project Description, Item ILE.

Item 1.a.1 (cost) -

The response is noted.

However, the instructions found in Item 3 page 32 of the application ask for a quote or proposal from an equipment vendor. In order to compare the amounts the applicant identifies in the Project Cost Chart and the table on page 33, please help facilitate the confirmation of the base equipment cost by providing the dollar equivalent of the **5,490,000,000 Japanese Yen** amount in the 1/17/2015 vendor quote.

The costs for shipping and installation appear to have been omitted from the \$64,839,450 equipment amount shown in the table as "CON Cost" and in the Project Cost Chart. The following definition regarding major medical equipment cost in Tennessee Health Services and Development Agency Rule 0720-9-.01 (13)(b) states " The cost of major medical equipment includes all

costs, expenditures, charges, fees, and assessments which are reasonably necessary to put the equipment into use for the purposes for which the equipment was intended. Such costs specifically include, but are not necessarily limited to the following: maintenance agreements, covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding.”

Please clarify the CON cost of the equipment by identifying the US dollar amount of the cost in the vendor quote. Please also confirm that the estimated total equipment cost of the project complies with Agency Rule by identifying the additional costs pertaining to shipping, government assessment (such as tariff on entry of equipment to US), and installation. If the amount is different than the entry for the Project Costs Chart, please revise the chart and submit a replacement page 52-R with your response.

2. Section B, Project Description, Item II.E

The response for Item 1.a.3 pertaining to clinical applications is noted. Review of the Medicare Administrative Contractor reference material pertaining to coverage for proton beam therapy provided in the response to question 4 (Cahaba Government Benefit Administrators L33070 effective 8/15/2013) appears to indicate that patients with Group 2 medical conditions, including prostate cancer and breast cancer, may be covered subject to the provision that the patient is enrolled in a clinical trial or national/regional clinical registry. Please describe the arrangements that will pertain to coordinating the patient’s treatment regimen in this regard, including the process that will be followed to document same in the patient’s clinical record/progress notes.

3. Section C, Need, Item 1

The responses are noted. With respect to Megavoltage Radiation Therapy Service, please address the following:

Item 6.e – what is the accreditation status of Provision’s proton therapy center in Knoxville with the American College of Radiation Oncology? Is it reasonable to expect that the applicant LLC’s experience will be similar?

4. Section C, Economic Feasibility, Item 2 (Funding) and Item 8 (Financial Viability)

The description of the funding support from the tax exempt bonds and clarification of the **Reserve Accounts** included in the applicant’s financing model to assure adequate cash flow and viability is noted. Please include a description that addresses the anticipated investment grade bond rating from Moody’s and Standard and Poor’s that may apply. Documentation of same in the form of an addendum to the 12/23/14 letter from Deutsche Bank Securities, Inc. (or memo) would be helpful in this regard.

5. Section C. II. Economic Feasibility, Question 9.

In the response to Item 4 (Section A, Item13) and Item 18 of your 2/24/15 supplemental response, the applicant notes that TennCare MCOs are currently providing coverage on a case by case basis and the Provsion Center in Knoxville is treating TennCare referrals out of contract on a preapproved basis.

As such, how was the estimated \$4.4 million in gross revenue determined for the 5% TennCare payor mix estimate on page 60 of the application? In your response, please estimate gross revenues for all payors in Year 1 of the project by completing the table below.

SHPTC Payor Source, Year 1

Payor Source	Gross Revenue	Gross Revenue by Payor Source (as a % of total)	Average Net Charge per Treatment
Medicare			
TennCare			
Managed Care			
Commercial			
Self-Pay			
Other			
Total		100%	

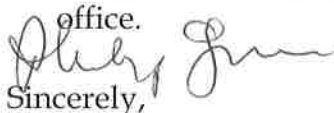
In accordance with Tennessee Code Annotated, §68-11-1607(c) (5), "...If an application is not deemed complete within sixty (60) days after written notification is given to the applicant by the agency staff that the application is deemed incomplete, the application shall be deemed void." **For this application the sixtieth (60th) day after written notification is April 23, 2015. If this application is not deemed complete by this date, the application will be deemed void.** Agency Rule 0720-10-.03(4) (d) (2) indicates that "Failure of the applicant to meet this deadline will result in the application being considered withdrawn and returned to the contact person. Re-submittal of the application must be accomplished in accordance with Rule 0720-10-.03 and requires an additional filing fee." Please note that supplemental information must be submitted timely for the application to be deemed complete prior to the beginning date of the review cycle which the applicant intends to enter, even if that time is less than the sixty (60) days allowed by the statute. The supplemental information must be submitted with the enclosed affidavit, which shall be executed and notarized; please attach the notarized affidavit to the supplemental information.

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Should you have any questions or require additional information, please contact this office.


Sincerely,

Philip Grimm, HSDA Examiner